

Laboratory
Report No. 31

CLINICAL INVESTIGATION PROGRAM

30 SEPTEMBER 1995

ANNUAL PROGRESS REPORT

FITZSIMONS ARMY MEDICAL CENTER

DEPARTMENT OF CLINICAL INVESTIGATION

DTIC QUALITY INSPECTED 3

Aurora, CO 80045-5001

19960718 086

DISTRIBUTION STATEMENT 4

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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE 30 Sep 95	3. REPORT TYPE AND DATES COVERED Annual FY 95 1 Oct 94 - 30 Sep 95	
4. TITLE AND SUBTITLE Annual Progress Report (U) (APR) Clinical Investigation Program RSC MED-300			5. FUNDING NUMBERS	
6. AUTHOR(S) Scott D. Bennion, COL, MC				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Department of Clinical Investigation Fitzsimons Army Medical Center Aurora, CO 80045-5001			8. PERFORMING ORGANIZATION REPORT NUMBER MCHG-CI RSC MED-300	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Clinical Investigation Regulatory Office AMEDD C&S ATTN: HSMC-GCI 1608 Stanley Road Ft. Sam Houston, TX 78234-6125			10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES The findings in this report are not to be construed as an official Dept. of the Army position unless so designated by other authorized documents.				
12a. DISTRIBUTION/AVAILABILITY STATEMENT NA Distribution Unlimited Approved for Public Release			12b. DISTRIBUTION CODE DOE	
13. ABSTRACT (Maximum 200 words) Subject report identifies these individuals who are conducting investigative protocols at Fitzsimons Army Medical Center. An abstract of each protocol giving abbreviated technical approach, objectives, and progress is presented. Publications and Presentations by Fitzsimons Army Medical Center professional staff.				
14. SUBJECT TERMS			15. NUMBER OF PAGES 335	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT UL	

REPORTS CONTROL SYMBOL MED-300

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DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045-5001

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FOREWORD

This report highlights the research activities conducted by Fitzsimons Army Medical Center investigators during Fiscal Year 1995 as well as presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations. In conducting the research described in this report, the investigator(s) adhered to AR 70-18, The Use of Animals in DOD Programs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is grateful to the Center's Commanders, BG J. Sutherland Parker, and COL Arlene J. Zaloznik, and all of the professional and administrative staff for departments and directorates who have furthered the mission of Clinical Investigation Department at Fitzsimons through their cooperation and efforts. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Assistant Chief, LTC Michael Lieberman, the Chief, Cell Physiology Service, Ronald Jackson, PhD, the Research Protocol Specialist, Ms. Marcia Bilak, and Secretary, Ms. Chris Montoya, without whose assistance and support this year's progress and its report would not have been possible.

SCOTT D. BENNION
COL, MC
Chief, Department of
Clinical Investigation

UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY95 culminated in the publication of 62 articles and 101 presentations and lectures at national, international, and regional scientific meetings. As of 30 Sep 94 there were 231 ongoing protocols. Over the course of the year there were 303 active protocols. Seventy-two new studies were approved and 173 studies were completed or terminated. At the start of FY96 (1 Oct 95) there were 130 ongoing protocols.

Objectives: To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medical education. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field. Investigators are encouraged to seek extramural funding based on preliminary data obtained from in-house studies.

Technical Approach: This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23,

Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Staff of the Department of Clinical Investigation:

Position	Name	Grade/Branch	MOS
<u>Office of the Chief</u>			
Chief	Bennion, Scott D.	06/MC	60G8N
NCOIC	Wilson, Elizabeth	E6	91K30
Research Prot Spec	Bilak, M. Marcia	09/GS	0301
Secretary	Montoya, L. Chris	06/GS	0318
<u>Animal Resource Service</u>			
Chief	Corcoran, Kevin	04/VC	64C9B
NCOIC	Bowers, Anthony	E6	91T3R
Animal Care Spec	Bayles, James	E6	91T3R
	Burgess, Kathleen	E5	91T2R
OR Nurse	Wehba, Kathy	10/GS	
OR Tech	Selman, Kurtis	E4	91D2R
	Alford, Eric	E3	91T25
Animal Care Foreman	Chase, Charmaine	04/WS	5048
Animal Caretaker	Giese, Penelope	05/WG	5408
	Ferguson, John	05/WG	5408
<u>Cell Physiology Service</u>			
Chief	Jackson, Ronald	13/GM	1320
Bio Sci NCO	Johnson, Thomas	E6	91K3R
Bio Sci Asst	Schaphorst, John	E5	91K1P6
	Nystrom, Steven	E4	91K1P6
	Horton, Heidi	E4	91K1P6
Microbiologist	Hoyt, Ann	11/GS	0403

Immunology Service

Chief	Lieberman, Michael	05/MS	68T00
Microbiologists	Lima, Joseph	11/GS	0403
	Meuhlbauer, Sheri	11/GS	0403
Med Technologist	Sachanandani, D.	09/GS	0644

Microbiology Service

Chief	Harris, Richard	05/MS	68A00
Bio Sci NCO	Sipple, Jeffrey	E4	91K1P6
Microbiologist	Paine, Donald	11/GS	0403
Research Chemist	Noble, Sharon	11/GS	1320
Med Technicians	Nelson, Sharon	07/GS	0645
	Revello, Rank	07/GS	0645

Molecular Biology Service

Chief	Gutierrez, Anthony	13/GS	1320
Research Chemist	O'Brien, Judith	11/GS	1320
Microbiologist	Andreatta, C.	11/GS	0403

Biometrics & Research Design Service

Chief	Damiano, Melissa	09/GS
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Personnel

	Required	Authorized	Assigned
Officers	7	3	4
Enlisted	12	5	11
Civilian	34	22	21

FUNDS: The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

Civilian Personnel	\$878,005
Contracts	53,729
Consumable Supplies	381,606
CEEP Equipment	77,002
Travel	28,991
Print/Publication	5,921
MEDCASE	0

GRANTS FOR FY95:

USAMRMC \$96,195 Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents. This grant supports a contract nurse.

Other federal grant \$2,700

Henry M. Jackson Foundation for the Advancement of Military Medicine \$7,005

Colorado Biomedical Foundation \$41,799

Defense Women's Health Research Program: Congress authorized a \$20,000,000 Army appropriation for research on women's health issues related to service in the armed forces. In March, 1995, funds were released for research to be completed by June, 1996. A total of 98 proposals were submitted from Army hospitals with 44 submitted by FAMC. Of the Army's submissions 35 were approved in the amount of \$2,805,204. The following studies from FAMC were approved and funded for a total of \$1,082,870:

\$264,500 Chest Pain Syndromes in Active Duty Women: Screening and Diagnosis. Jennifer L. Calagan, MAJ, MC, Cardiology.

\$148,500 The Non-Invasive Detection and Characterization of Anal Incontinence in the Female Population. Bradley Bute, MAJ, MC, General Surgery.

\$139,735 Relationships Between a Female Soldier's Military Occupational Speciality (MOS) and Birth Outcomes. Joseph Creedon, CPT, MS (PA), Occupational Health Svc, EACH, Fort Carson

\$130,900 Gastrointestinal Lesions in Iron Deficient Premenopausal Women. Thomas Kepczyk, MAJ, MC, Gastroenterology.

\$123,251 Simultaneous Transmission/Emission Protocol (STEP) for Attenuation Correction of Breast and Diaphragmatic Attenuation Artifacts During SPECT 99mTc-Sestamibi Myocardial Perfusion Scans in Patients without Coronary Artery Disease. Mike McBiles, LTC, MC, Nuclear Medicine.

\$121,600 Evaluation of the Performance Impact and Treatment of Exercise Induced Urinary Incontinence Among Female Soldiers. Gary Davis, COL, MC, Gynecology. This study moved to MAMC when the investigator PCS'd.

\$103,034 Evaluation of a Structured Physical Fitness Program for Pregnant Soldiers: Effects on Weight Gain, Blood Pressure, Lost Duty Time, Length of Labor, and Ability to Pass Physical Training Test Post Delivery. Elizabeth M. Wanersdorfer, COL, AN, Nursing.

\$35,809 The Effects of Region-specific Resistance Exercises on Bone Mass in Premenopausal Military Women. Michael McDermott, LTC, MC, Endocrinology.

\$15,541 Assessment of Dietary Calcium Intake, Physical Activity and Habits Affecting Skeletal Health Among Premenopausal Military Women. Michael McDermott, LTC, MC, Endocrinology.

Facilitators of Applied Clinical Trials (F.A.C.T.)
Support to Army Medical Institutions
October 1, 1994 - September 30, 1995

Institution	Personnel	Trips	Property & Services	Total
FAMC	\$72,523.84	\$32,922.24	\$11,603.00	\$117,049.08
Defense Women's Health Research Program				
FAMC-Based Projects (4 sites)				
	111,195.38	562.23	197,047.51	308,805.12
Ft Carson-Based Project (5 sites)				
	36,570.56	0.00	12,733.38	49,303.94
MAMC-Based Project (1 site)				
	53,163.20	3,263.42	14,971.85	71,398.47
TOTAL DWHRP	\$200,929.14	\$3,825.65	\$224,752.74	\$429,507.53

ANIMAL RESOURCES SERVICE

Training Support Summary, FY 95

One exercise was conducted in "Resuscitation of Newborn" for the American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Eighteen physicians, nurse practitioners, and midwives received four hours of training in methods of resuscitation and endotracheal intubation, using eleven ferrets and requiring ten hours of support by Animal Resources Service personnel, administering and monitoring anesthetic and cleanup. The ferrets were recovered and returned to the colony for re-use.

Five rats were utilized in support of microsurgery training in the re-anastomosis of small vessels, providing ten hours of training for four staff surgeons and fellows from Plastic Surgery Service. Support of this training by Animal Resources Service personnel totalled fifteen hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

Five rats were used in support of microsurgery training in the re-anastomosis of small vessels, providing ten hours of training for a total of four staff surgeons and residents from the Orthopedic Surgery Service. Support of this training by Animal Resources Service personnel totalled fifteen hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

A total of three opossums and two goats were utilized for the training of Animal Resources Service personnel. Seven animal care personnel received five hours of in house training in husbandry, endotracheal intubation, restraint and phlebotomy techniques.

A total of two goats were utilized in support of training of laparoscopic techniques, providing eight hours of training for six residents from General Surgery Service. Support of this training by Animal Resources Service personnel totalled nine hours, monitoring anesthesia, cleanup, and instrument cleaning and sterilization.

A total of two goats were utilized in support of training of laparoscopic and thorascopic techniques, providing four hours of training for four residents from Neurosurgery Service. Support for this training by Animal Resources Service personnel totalled eight hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

A total of two pigs were utilized in support of training of laparoscopic techniques, providing four hours of training for six

residents from General Surgery Service. Support for this training by Animal Resources Service personnel totalled eight hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

A total of two pigs were utilized in support of training of laparoscopic techniques, including nephrectomy, vein ligation and lymph node dissection, providing four hours of training for six residents from Urology Service. Support for this training by Animal Resources Service personnel totalled eight hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

Cost of Training

Ferret Intubation	\$2.00/animal x 11 animals = \$22.00
Goat Laparoscopy	\$200.00/animal x 4 animals = \$800.00
Pig Laparoscopy and Laparotomy	\$220.00/animal x 4 animals = \$880.00
Rat Microsurgery	\$24.00/animal x 10 animals = \$240.00
In House Training	Total for all animals used = <u>\$25.00</u>
TOTAL	\$2302.00

CELL PHYSIOLOGY SERVICE - FY 95

Localization of antigen components involved in autoimmune blistering skin diseases of the dermal-epidermal junction or basement membrane zone (BMZ) has continued. Evaluation of skin BMZ using gold-antibody conjugated nanoprobe and transmission electron microscopy has demonstrated antigenic sites involving these disease-associated antigens. Gold-conjugated antibodies to laminin, Type IV collagen, and GB3 have been investigated using sectioned adult or neonatal skin samples. Positive results have been demonstrated with the adult specimens. Similar procedures are presently being tested utilizing neonatal skin. These findings will validate procedures which may have potential use in diagnosing autoimmune type diseases, specifically a split-skin technique. Separation of the epidermis from the dermis of a collected skin specimen (split), when combined with immuno-fluorescence staining may improve current clinical methods for identifying certain blistering skin disorders. Results from this study (91-125) were presented by Dr. Kathleen David-Bajar at the Western Society of Investigative Clinical Research (Jan 95).

The diagnostic value of using monoclonal antibodies in identifying particular skin tumors or disorders is continuing under protocol 134-91. It is reported that some monoclonal antibodies lack the specificity to identify a particular neoplastic antigen. Epidermal cells including keratinocytes and melanocytes have been isolated from normal human skin and cultured singly or in combination to

study the expression of certain disease-associated antigens. Culture conditions were altered to mimic various pathologic environments. Pre-confluent, cultured keratinocytes are utilized to simulate acantholytic round cell carcinoma and will be compared with post-confluent keratinocytes (normal state) for binding antigens, vimentin and cytokeratin. Melanocytes grown individually or in combination with keratinocytes are being investigated for the expression of HMB-45, an antigen associated with melanocytes in malignant melanomas. Immunology Service has evaluated antibody binding using Fluorescence Assisted Cell Sorting (FACS). Data on keratinocytes grown to confluency compared to pre-confluent cells show that vimentin antigens are expressed by cells under both conditions at similar levels. Cultured normal melanocytes in pure cell cultures or in combination with keratinocytes do not stain for HMB-45. These findings suggest that some monoclonal antibodies may possess a high degree of specificity for neoplastic antigen identification.

CPS completed work for a study to determine the feasibility of establishing ovine chondrocyte cultures. Cultures of ovine chondrocytes which were derived from both fetal and adult articular cartilages have been established. Chondrocytes were grown and passaged onto a collagen-matrix coated and noncoated culture flasks. Growth characteristics and morphological evaluations have established the growth profiles of these cell types. This work was in support of Orthopedic residency training for CPT Shawn Granger.

Dr. Martin Johnson, an Air Force research Fellow, is studying graft versus host (GVH) disease utilizing a RF leukemic mouse strain. Bone marrow/splenocyte (BM/SC) cells from Balb C donor mice are irradiated and then transplanted to recipient RF strain mice in which leukemia has been induced. Groups of leukemic mice are transplanted with BM/SC cells that receive ultraviolet B radiation (UVB) or non-irradiated BM/SC cells. Irradiation of BM/SC inoculum is hypothesized to reduce GVH disease and decrease the incidence of a leukemic relapse. Earlier studies have established the dose-response of x-ray irradiation and induction of leukemia in RF strain mice. This phase has demonstrated success with leukemia confirmed in irradiated RF mice. Surgical removal of bone marrow/splenocytes and dose response curves using UVB which establishes viability for allogenic BM/SC derived cells have been completed. Results have demonstrated that graft failure has occurred in nearly all recipients.

Dr. Thomas McGovern, Dermatology resident, is investigating the use of ultraviolet B-exposed skin to detect abnormal cytokine response in primary pulmonary hypertensive (PPH) patients. Very little information is known about the pathogenesis of PPH. In PPH abnormal levels of circulating cytokines or anomalies in endothelial/epithelium interactions are proposed as underlying the pathology of this lung disease. It is hypothesized that the skin in these patients may also demonstrate abnormally high expression

of cytokines or abnormalities in endothelial/epithelium interactions, thus becoming a possible test site to determine the severity of this disease. At present, five normal control subjects and five patients with PPH have had skin biopsies performed for baseline parameters and compared to 24 and 48 hours post UVB irradiation (exposure equivalent to mild sunburn) samples. Histology has been completed for H & E, and Hoechst stains to determine presence of inflammatory cells and tissue pathology as well as cell apoptosis. Evaluation with immunocytohistology is being performed to stain for immunoreactants, cytokines, adhesion molecules, Langerhans cell density and dendricity, as well as tissue and serum interleukin-1. Preliminary results from this study will be presented at a later conference.

Immunology and Cell Physiology are collaborating with Dr. Harold Vogel, a neurosurgeon from Denver General Hospital. Dr. Vogel is attempting to differentiate malignant rat glial cells grown in culture by exposing them to media which originally supported growth of fetal rat cells. The hypothesis tested is that malignant brain cells act similar to fetal cells with the way they grow. Their growth patterns appear to be "unchecked" in that the normal growth controls usually found in the adult state are absent. If fetal control systems could be reapplied, malignant cells might redifferentiate and become subject to the usual adult homeostatic mechanisms. Tumor Malignancy evaluated by flow cytometry analyzed the relative measurements of ploidy, aneuploid/euploid peaks. The original hypothesis was proven invalid. However, a pilot experiment was performed to elicit differentiation of malignant cells by exposing them to media of a different composition plus 2% dimethyl sulfoxide (DMSO). This change seemed to temporarily induce differentiation as measured by the disappearance of tumor aneuploid peaks. Investigation continues under a new protocol. This approach will examine cell differentiation brought about by use of placental lactogen contained within an encapsulated-liposome system in combination with a solvent which will permit cell entry. An abstract has been submitted for presentation at the American Association of Neurological Surgeons meeting, April 1996.

Dr. Grammar-West, Dermatology resident, completed a research project entitled "Comparison Testing of the Irritancy of Hand Dishwashing Liquids Using Modified Patch Testing Methods" (Protocol # 95-113). The purpose of this study was to compare the irritancy of ten common name brand dishwashing liquids and determine if "sensitive skin" formulas were less irritating than regular ones. Sixteen subjects were exposed to dilute soap concentrations by use of a modified patch testing method similar to that used to test reactions of patients to allergens. All detergents produced some degree of irritation. However, newer formulations (sensitive skin formulas) demonstrated little irritant effect. Results from this study suggest that patients who exhibit dermatitis reactions to constant use of liquid dishwashing soaps may

find less irritating reactions to newer formulations. Findings were published in the *Journal of the Academy of Dermatology*.

CPS provided electron microscopic support in collaboration with the University of Colorado Health Sciences Center investigating the identification of human hair follicle outer root sheath (ORS) melanocytes. It is believed that ORS melanocytes are the reservoirs for repopulation of epidermal melanocytes during re-epithelization for loss of epidermis and repigmentation in vitiligo (loss of skin pigment). Immunoelectron microscopy was performed using naonogold conjugated-antibodies with silver enhancement specific for identifying premelanosomes related antigens. The majority of ORS melanocytes were found in the mid to the upper portion of the hair follicle. A manuscript will be published in the *Journal of Investigative Dermatology*.

CPS supported eleven protocols during this period. There were: 5 cell culture, 4 human use, and 2 animal protocols. One fellow, three residents and three staff clinicians trained in FY95. There were three collaborative projects with outside agencies such as UC Health Sciences Center, Denver General Hospital and Albert Einstein College of Medicine, Bronx, New York. CPS work resulted in 3 abstracts, 3 presentations, and 2 published manuscripts this fiscal year.

IMMUNOLOGY SERVICE - FY 95

The Immunology Service, Department of Clinical Investigation, provides clinical immunology laboratory support and performs basic and clinical immunology research. Studies of both cellular and humoral immunity are conducted. Major areas of emphasis include flow cytometry, antigen and antibody analysis by enzyme-linked immunosorbent assays (ELISA), and functional studies of immunocompetent cells, such as mitogen and antigen stimulated lymphocyte transformation assays, opsonophagocytosis (bactericidal) and chemiluminescent assays on neutrophils, and natural killer (NK) cell cytotoxicity assays. Flow cytometry is used for lymphocyte immunophenotyping in HIV and other immunodeficient and autoimmune patients, leukemia and lymphoma typing, and DNA and cell cycle analysis in breast cancers. Also, cells from selected patients cultured in vitro with various mitogens or cytokines are analyzed for the expression of "activation" or "memory cell" markers by flow cytometry, and for the production of immunoglobulins or cytokines by ELISA. In addition, various other immunochemical procedures are performed, such as electrophoresis and immunoblotting of antigens and antibodies ("Western blots") in specimens from autoimmune patients and analysis of serum proteins by rate nephelometry.

Currently, the Immunology Service is actively supporting protocols originating from the Allergy/Immunology, Dermatology, Gastroenterology, Infectious Disease, and Pulmonary Services, as well as the Departments of Surgery, Pediatrics, Primary Care, and Clinical Investigation.

CLINICAL BIOMETRICS AND RESEARCH DESIGN SERVICE - FY95

Orthopedic and General Surgery residents rotate through the Service as part of their regular training programs. Each resident spends two 2-week rotations learning clinical research design, statistics, computer and data processing. They also plan, write and initiate a research project thus allowing them to become familiar with the specifics of managing a research protocol. Mrs. Damiano presented formal courses in research design, statistics and responsible conduct in research.

MICROBIOLOGY SERVICE - FY95

A study with the Allergy Service is comparing the efficacy of various procedures for pollen allergens used in skin testing. A comparison of extraction procedures using Russian thistle pollen was completed and a manuscript was prepared for journal submission. A study examining microbial contamination of pollen extracts is completed.

A protocol examining Hepatitis C infections in military families was completed. The Microbiology and Molecular Biology Service jointly investigated genetic variation of the Hepatitis C envelope hyper variable region in HIV co-infected patients.

An HIV natural history study in collaboration with FAMC Infectious Disease Service and the Department of Diagnostic Retrovirology at WRAIR is providing information on the development of AZT resistance at the molecular level in HIV-infected patients. The patient data base has been used to analyze the impact of AZT therapy on disease progression at various stages of HIV disease. An analysis of patterns of AZT resistance is being conducted on HIV strains of patients' samples within 1 year of seroconversion.

The Service supported a study of urine and serum arsenic concentrations following melarsoprol therapy in a patient with trypanosomiasis. The Microbiology Service and the Inpatient Pediatric Service completed a protocol examining gamma-interferon therapy on Group B Streptococcal sepsis in neonatal rats. A survival study of combination treatment with gamma-interferon and penicillin was completed.

Several laboratory studies were completed in support of a protocol by the Endocrine Service examining bone density in thyroid extract-treated patients and in support of a protocol by the Pulmonary Service examining the effect of recombinant growth hormone on pulmonary function in patients with COPD.

MOLECULAR BIOLOGY SERVICE - FY 95

The assigned staff of the Molecular Biology Service are Dr. Anthony G. Gutierrez, Chief, GS-13, Ph.D. in Molecular Genetics, and Ms. Judith O'Brien, Research Associate, GS-11, Chemist. The Service benefitted from the intradepartmental transfer assignment of Cindy Andreatta, GS11, from the Microbiology Service.

In September of 1995 approximately \$600K equipment inventory was laterally transferred from DCI, FAMC to the Center for Health Promotion and Preventive Medicine (CHPPM) through the FAMC DOL. This was done in anticipation of equipment turn-in due to upcoming BRAC termination of DCI mission and to ensure continuity of the mission-essential capabilities of FAMC tenant unit and DCI collaborator, CHPPM. This equipment remains on hand at DCI until mission termination in July of 1996, at which time CHPPM will take formal possession of the equipment.

Ongoing Protocols:

Rapid Identification of Sandfly Species and Strains using Randomly Amplified Primed DNA (RAPD). In November, 1995, LTC Patrick Supon, Chief, Microbiology Service, began a collaboration in the Molecular Biology Service with CPT Miguel Quintana, WRAIR to identify sandfly species and strains associated with leishmaniasis.

Detection of Measles RNA in Intestinal Tissue Samples from Patients with Crohn's Disease by a Polymerase Chain Reaction Assay. Scot Lewey, MAJ, MC, Principal Investigator; Kenneth E. Sherman, MD, and John Singleton, MD, Associate Investigators. Primers were synthesized and reverse transcription and PCR methods were optimized for detection of measles virus in colon. Biopsy samples of colon tissue were collected from patients with inflammatory bowel disease. Abstract published in Gastroenterology, Vol. 108(4) A861, April 1995.

A Method of Detecting M. Paratuberculosis using PCR Without Southern Blot. Scot Lewey, MAJ, MC, Erik Mondrow, MD, St. Joseph's Hospital, Investigators. Developed a PCR procedure using nested primers for detection of *Mycobacterium paratuberculosis*, which causes Johne's disease in ruminants and has been implicated in Crohn's disease as well. Abstract published in Gastroenterology, Vol.108(4) A879, April 1995.

FAMC 91-300: Hepatitis C in Pregnancy: Viral Titers and Thymosin Levels. Kenneth E. Sherman, MD, Principal Investigator; Judith O'Brien, DAC, Associate Investigator. Samples were collected at the University of Colorado Health Sciences Center. PCR for hepatitis C was completed on all samples including cord blood in May, 1995. FAMC DCI participation in protocol was terminated by DCI in May 1995 because Dr. Sherman has separated from the Army.

Development and Analysis of a Sensitive and Specific Assay to Detect Melanoma Cells in the Peripheral Blood of Patients with Melanoma. Patrick Walsh, MD, Marti Friednash, MD, USCHSC, and Scott Bennion, COL, MC, Investigators. Developed method to isolate mRNA from circulating melanocytes and detect tyrosinase positive cells by RT-PCR. The assay enables the clinician to determine whether melanoma cells have invaded the bloodstream.

Epidermal ICAM-1 Expression is not a Primary Inducer of Cutaneous Inflammation in Transgenic Mice. Kathy David-Bajar, MD, LTC, MC, Principal Investigator. Developed method to detect human growth hormone (HGH) gene used as a marker in transgenic mice. Performed PCR for HGH and mouse beta-actin on mouse tail clippings to separate transgenic from non-transgenic mice.

Use of a Degenerate, Nested Primer PCR Technique for Non-Invasive Detection of Anogenital Human Papillomavirus in Males. Clive Daniels, CPT, USAF, MC, Principal Investigator; Anthony Gutierrez, PhD, and Judith O'Brien, DAC, Associate Investigators. Primers were synthesized and PCR method optimized for detection of HPV. Dr. Daniels collected samples at the US Naval Medical Center, San Diego, CA, and sent them to FAMC for PCR. PCR was completed in December, 1995. Manuscript is in preparation.

Sequencing of E2/NSI Hypervariable Region of Hepatitis C: Cindy Andreatta, Dr. Harris. Project was completed, manuscript is to be published in April 1996 Hepatology.

Throughout the year, William Irwin and other personnel from the Army Environmental Health Sciences Agency have worked in the Molecular Biology Laboratory. They received training on the synthesis of primers, DNA extraction and PCR for the detection of *Borrelia burgdorferi*, *Ehrlichia chaffeensis*, and other pathogens in insect vectors.

HUGH MAHON LECTURESHIP AWARD COMPETITION - 1995

This student research award was established in 1950 and honors the late Colonel Hugh W. Mahon, MC, USA, Retired, who was Chief, Department of Pathology, Fitzsimons Army Medical Center, for 12 years. The lectureship consists of the presentation of papers judged best from among those submitted by officers in training status at FAMC.

This year the Hugh Mahon Lectureship Award Competition was divided into three categories. Literature reviews and case reports were one category with ten manuscripts submitted. The clinical category had nine submissions, and there were eight papers submitted in the laboratory category, for a total of 27 manuscripts in competition. In 1994 there were 30 submissions; in 1993, 28; in 1992, 38 submissions; in 1991, 34; in 1990, 36; in 1989, the largest with 41; in 1988, 23; and in 1987, 18.

Judging was performed by the members of the FAMC clinical teaching staff. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

The first and second prize winners were chosen from among the finalists each of the three categories based on the presentation and question-and-answer period during the Hugh Mahon Lectureship Conference.

The finalists for 1995 are as follows:

Clinical

1st Place Usefulness of the American College of Rheumatology Recommendations for Liver Biopsy in Methotrexate-Treated Rheumatoid Arthritis Patients. Alan R. Erickson, MC, Rheum/Med.

2nd Place Comparison of Three Pneumatic Compression Devices for the Prevention of Deep Venous Thrombosis After Joint Replacement Surgery: Preliminary Report. Mark E. Clyde, CPT, MC, Orth/Surg.

Laboratory

1st Place Development of an Infection Resistant External Fixator System and a Metatarsally Implanted Percutaneous Limb Prosthetic Holder. Lori E. Harrington, MC, Orth/Surg.

2nd Place A Comparison of Patellar Tendon Graft Fixation Techniques in Anterior Cruciate Ligament Reconstruction Using a Goat Model. Paul H. Castello, MC, Orth/Surg.

Case Report/Literature Review

1st Place Cutaneous Manifestations of African Trypanosomiasis. Thomas W. McGovern, CPT, MC, Derm/Med.

2nd Place Gamma Delta T-Lymphocytosis in a Patient with Common Variable Immunodeficiency. Rohit K. Katial, MC, All-Imm/Med.

A HISTORY OF RESEARCH AT FITZSIMONS ARMY MEDICAL CENTER

The roots of Fitzsimons' clinical research can be traced back over five decades. In 1941 the US Army Medical School at Walter Reed General Hospital began an instructional program to teach officers about military nutrition. Eventually, the school added military nutritional research as part of its mission.

By September of 1944 the Office of the Surgeon General moved the program and its mission to Chicago and established the US Army Medical Nutrition Laboratory (USAMNL). In May 1947, a joint project was started between USAMNL and Fitzsimons General Hospital. Its focus was to study the effects of nutrition on lung diseases, especially the use of vitamin A on bronchiectasis. Later that year the Research and Development Unit was established at Fitzsimons. The Unit was headed by 1Lt Edward Liddle and had an authorized strength of 7 officers, 7 enlisted and 8 civilians to run the Administrative Section, and to perform research in the Microbiology Lab and the Special Metabolic Lab.

In the fall of 1953 the USAMNL was transferred from Chicago to Fitzsimons, and in 1958 it was combined with the R & D Unit to become the US Army Medical Research and Nutrition Laboratory (USAMRNL). During the next 14 years the USAMRNL research mission produced outstanding findings in such areas as: medical nutrition and physiology of starvation, I.V. parenteral nutrition, especially the use of fat emulsion therapy, the treatment of tuberculosis, the irradiation of foods project, and the effects acute high terrestrial altitude on human physiological functions (the Altitude Research Lab is still located on the summit of Pike's Peak).

In 1972 the USAMRNL was relocated to the new Letterman Army Institute of Research (LAIR), and on 24 August 1973 the USAMRNL was discontinued as a Fitzsimons activity. Research, however, continued at Fitzsimons under the Clinical Research Services which was later renamed Clinical Investigation Services (CIS). Finally, in 1983, CIS was changed to the Department of Clinical Investigation (DCI) and has remained so until the present.

DCI is located in three buildings just east of the hospital. The main building (601) houses the Administrative Services, the Animal Resources which includes the Surgical Support Branch, Immunology Service, Cell Physiology Service and Microbiology Service. Building 610 is a 7000 sq ft animal facility which has had the distinc-

tion of being accredited by the American Association for Accreditation of Laboratory Animal Care since Feb 1985. The third building (600) contains the Biochemistry Service and the newer, state-of-the-art Molecular Biology Service (1991-92).

The mission of DCI has been to actively encourage and support the Graduate Medical Education Program through training and teaching of resident clinicians and providing research assistance in six functional areas. Clinicians performing research can receive assistance through all phases of the research process to include: protocol design and development, conduct of experimentation, collection of data, statistical analysis and interpretation, and help in writing reports, abstracts, or manuscripts for publication. The Chief of DCI resides as Chair of the Institutional Review Committee and the Institutional Animal Care and Use Committee which reviews new research protocols for protection of subjects' (human and animal) rights and safety as well as for scientific merit. A research protocol specialist and an animal research coordinator assist the chief in this process by preparing protocols for committee review and by assisting in questions regarding Army regulatory guidance.

Since the inception of research at FAMC, the members of the staff of the USAMRNL, the R & D Unit, Fitzsimons Hospital and the Clinical Investigations activities have produced over 341 numbered OTSG reports, more than 36 unnumbered reports and reports from other agencies, thousands of abstracts and presentations, and greater than 3700 publications in the scientific literature. The Department of Clinical Investigation and Fitzsimons Army Medical Center have collaborated with UC Health Sciences Center, Colorado State University, Denver General Hospital and other hospitals in the metro area, national Oncology agencies, the Medical Research and Materials Command, the National Cancer Institute, NIH and many organizations in important health care endeavors.

The Department of Clinical Investigation will close its doors for the last time on 31 July 1996. COL Scott D. Bennion, Chief of DCI, would personally like to express his appreciation and gratitude to all the staff, investigators, clinicians, nurses, volunteers and those many people who have given their support and whose contributions have been vital to the highly successful clinical research effort at Fitzsimons.

Source: *Three Decades of Endeavor - a Bibliography: 1944 -1974.* By A.J.Kuemmerlin, B.L.Wilson, Y.M.Rhodes, and J.E.Canham, COL, MC.

PRESENTATIONS - FY95

*** = Protocol Related**

Deputy Commander

Zaloznik A: Screening mammography use: A comparison of four racial groups. ASCO Meeting, April 1995.

Department of Clinical Investigation

*Corcoran KD: Testing an inbone anchored percutaneous limb prosthetic holder in goats - The first six months. Mile High Branch, Association for Laboratory Animal Science, Silver Creek, CO, May, 1995

*Vogle HB: A series of ENU induced tumors in a Fisher CDF rats. Minneapolis, MN Apr-May 1996.

*Sherman R, Lisecki E, Harrington L: Development of an infection resistant external fixator system and a metatarsally implanted percutaneous limb prosthetic holder: Denver, CO, March 1995.

Department of Medicine

Kator SF, Shea RJ, Bair M: Utility of preoperative chest radiographs. Colorado Springs, CO, February 1995.

Edavettal J, Coats E: Acute psychosis? Colorado Springs, CO, February 1995.

Alkadi D: Lipodystrophy: A zebra that sounds like a horse. Colorado Springs, CO, February 1995.

Dermatology Service

*David-Bajar K, Johnson T, Jackson R, Bennion S: Comparison of neonatal vs adult skin as substrate for split skin indirect immunofluorescence. Carmel, CA, February 1995.

McGovern TW, Zumbro DS, Erickson AR: A comparison of conjunctival and nailfold capillary microscopy in patients with systemic sclerosis. New Orleans, LA, 5 Feb 95.

McGovern TW, Gentry RH: Cutaneous manifestations of African Trypanosomiasis in a 67 y/o male. New Orleans, LA, 4 Feb 95.

Infectious Disease Service

Winters G, Gates R: Community acquired capnocytophaga meningitis. Local ACP Meeting, June 1995.

Internal Medicine Service

Dubravec MS, Battafarano N, Spaulding HS: Anaphylaxis and the school setting: A survey. Denver Metropolitan area, Feb - April 1995.

Houser A, Huber J, Williams W: Beta hemolytic streptococcus group G infection: an unusual presentation. Colorado Springs, CO, February 1995.

Houser A, Huber J, Williams W: Salmonella arizonae bacteremia in a patient with systemic lupus erythematosus. Colorado Springs, CO, February 1995.

*Hsue G, Williams W: East African trypanosomiasis with CNS invasion in an American traveler. Colorado Springs, CO, February 1995

Rheumatology Service

Erickson A, Bray V, Enzenauer R: Rheumatic complaints in Persian Gulf War Veterans. Am Coll Rheum 1995 National Scientific Meeting, San Francisco, CA, 24 October 1995.

Medlillin M, Erickson A, Enzenauer R: Variability of treatment for gouty arthritis between rheumatologists and primary care physicians. Am Coll Rheum 1995 National Scientific Meeting, San Francisco, CA, 24 October 1995.

DEPARTMENT OF SURGERY

Orthopedic Service

*Castello PH, Lisecki EJ, Friedel SP, Samson MM: Randomized, prospective clinical and radiographic evaluation of hydroxyapatite-coated and uncoated porous total hip replacements. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

*Castello P, Hockenbury RT, Corcoran KD, McBride JT, Gillogly SD: A Comparison of patellar graft fixation techniques in anterior cruciate ligament (ACL) reconstruction using a goat model. Orlando, FL Feb 95, Am Acad Ortho Surg.

*Castello P, McBride J, Hockenbury RT, Gillogly SD, Corcoran KD: A comparison of patellar tendon graft fixation techniques in anterior cruciate ligament reconstruction using a goat model. Barnard Competition, Denver, CO, March 1995.

*Castello P, McBride J, Hockenbury RT, Gillogly SD, Corcoran KD: A comparison of patellar tendon graft fixation techniques in anterior cruciate ligament reconstruction using a goat model. 8th Annual AOA Zimmer Annual Travel Awards Competition for Orthopaedic Residents. White Sulphur Springs, WV, March 1995.

*Castello P, McBride J, Hockenbury RT, Gillogly SD, Corcoran KD: A comparison of patellar tendon graft fixation techniques in anterior

cruciate ligament reconstruction using a goat model. 42nd Annual Meeting of Mid-Central States Orthopaedic Society, Hot Springs, Arkansas, June, 1995.

*Castello P, McBride J, Hockenbury T, Gillogly SD, Corcoran K: A comparison of patellar graft fixation techniques in anterior cruciate Ligament (ACL) Reconstruction using a goat model. Vail, CO 8-10 Dec 94 Steadman-Hawkins Fellows Mtg.

*Castello P, Lisecki E, Friedel S, Samson M: Randomized, prospective clinical and radiographic evaluation of hydroxyapatite-coated and uncoated porous total hip replacements. Academy of Surgical Research, Albuquerque, NM, October 1995.

*Castello PH, Lisecki EJ, Fox MG, Rak KM, Lambert AT: Randomized, prospective clinical and radiographic evaluation of hydroxyapatite-coated and uncoated porous total hip replacements. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

Chang L, Chow G, Brown C: Spinal epidural abscesses: Summary of cases and review of the literature. Barnard Competition, Denver, CO, Mar 1995.

Chang L, Davis R: Surgical drain tube breakage and retention Pittsburgh, PA, Apr 95. Am Ortho Assoc.

*Chang L, Battista V, Jones DEC: Forearm Rotation in upper extremity casting. Am Ortho Assoc. Pittsburgh, PA, Mar 29-01 Apr 1995.

*Chang L, Battista VN, Jones DEC: Forearm rotation in upper extremity casting. Vail, CO, December 1995.

Chang L, Chow G, Brown C: Spinal epidural abscesses: Summary of cases and review of the literature. Academy of Surgical Research, Albuquerque, NM, October 1995.

*Clyde M, Nelson B, Lisecki E: Comparison of three pneumatic compression devices for the prevention of deep venous thrombosis after joint replacement surgery: Preliminary report. Barnard Competition, Denver, CO, March 1995.

*Clyde M, Nelson B, Lisecki E: The comparison of three pneumatic compression devices for the prevention of deep vein thromboses after joint replacement surgery Orlando, FL, Feb 95, Am Acad Ortho Surg.

*Clyde ME, Nelson BJ, Lisecki EJ: The comparison of three pneumatic compression devices for the prevention of deep venous thrombosis in total joint replacement patients: A prospective, randomized study. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

*Clyde ME, Nelson BJ, Lisecki EJ: The comparison of three pneumatic compression devices for the prevention of deep venous thrombosis in total joint replacement patients: A prospective,

randomized study. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

*Clyde M, Nelson B, Lisecki E: Comparison of three pneumatic compression devices for the prevention of deep vein thromboses after joint replacement surgery SOMOS, Hilton Head, SC Nov 94

*Clyde M, Nelson B, Lisecki E: Comparison of three pneumatic compression devices for the prevention of deep venous thrombosis after joint replacement surgery: Preliminary report. Academy of Surgical Research, Albuquerque, NM, October 1995.

*Clyde M, Nelson B, Lisecki E: Evaluation of three pneumatic compression devices following total hip and knee replacement surgery. Orlando, FL, February 1995.

*Farber G, Place H, Brown CW: Correlation of disc herniation and displacement in cervical fracture dislocations. Orlando, FL, Feb 95, Am Acad Ortho Surg.

*Farber, G, Place H, Damiano T: Assessment of pedicle screw placement with computed tomography versus anatomic dissection. North American Spine Society, 10th Annual Meeting, Washington, DC, October 1995.

*Farber GL, Place H, Damiano T; Assessment of pedicle screw placement with computed tomography versus anatomic dissection. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

*Farber G, Place H, Damiano T: Accuracy of pedicle screw placement as assessed by computed tomography versus anatomic dissection in cadaver spines. Barnard Competition, Denver, CO March 1995.

Farber G, Place H, Brown CW: Correlation of disc herniation and displacement in cervical fracture dislocations. Hilton Head, SC Nov 94

*Friedel S, Lisecki E: Comparison of three devices used for postoperative autologous blood transfusion. SOMOS, 36th annual meeting, Hilton Head, SC

*Friedel S, Lisecki E: Comparison of three devices used for postoperative autologous blood transfusion. 1995 Reconstructive Surgery of the Hip and Knee Course, Telluride, CO, March 1995.

*Friedel S, Topper SM, Jones DEC: Trigger finger: Effect of partial resection of a pulley on triggering. American Society for Surgery of the Hand, San Francisco, CA, September 1995.

*Friedel S, Topper S, Jones DEC: Trigger finger: Effect of partial resection of a pulley on triggering. Barnard Competition, Denver, CO, Mar 1995.

*Friedel SP, Lisecki EJ: Comparison of three devices used for postoperative autologous blood transfusion. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

*Friedel S, Topper S, Jones DEC: Trigger finger: Effect of partial resection of a pulley on triggering. Academy of Surgical Research, Albuquerque, NM, October 1995.

*Freidel S, Lisecki E: Comparison of three devices used for postoperative autologous blood transfusion. Orlando, FL, Feb 95, Am Acad Ortho Surg.

*Freidel S, Topper SM, Jones DEC: Comparison of three devices used for postoperative autologous blood transfusion. Vail, CO, December 1995.

*Granger SP, Lisecki EJ, Turner AS, Lonergan KT, Farriester BS; Biomechanical evaluation of radii from sheep which have undergone oophorectomy. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

*Granger S, Lisecki E, Turner AS, Lonergan K, Farriester S: Biomechanical evaluation of radii from sheep which have undergone oophorectomy. Academy of Surgical Research, Albuquerque, NM, October 1995.

*Granger S, Lisecki E, Turner AS, Lonergan K, Farriester S: Biomechanical evaluation of radii from sheep which have undergone oophorectomy. Barnard Competition, Denver, CO, Mar 1995.

*Granger S, Lisecki EJ, Turner AS, Lonergan K, Farriester S: Biomechanical evaluation of radii from sheep which have undergone oophorectomy. Vail, CO, December 1995.

*Grant M, Jones DEC, Karstetter K, Sherman R: Control of swelling after foot surgery using pulsed, high frequency electromagnetic energy. Barnard Competition, Denver, CO, Mar 1995.

*Harrington, LE, Sherman RA, Lisecki EJ, Corcoran KD: Development of a percutaneous limb prosthetic holder in a goat model study. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

*Kim DH, Reister JA, Lisecki EJ: Bipolar vs unipolar hemiarthroplasty: A comparison of in vitro stability. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

Kim DH, Patel AI, Brown CW, Friermood TG; Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome: Preliminary review of results. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

Kim D, Patel AI, Brown CW, Friermood TG: Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome. 42nd Annual Meeting of

Mid-Central States Orthopaedic Society, Hot Springs, Arkansas, June, 1995.

Kim DH, Patel AI, Brown CW, Friermood TG: Arthrodesis of the sacroiliac joint syndrome. Preliminary reviews of results. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

Kim DH, Patel AI, Brown W, Friermood TG: Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome: preliminary review of results. Smith & Nephew Richards, 13th Annual Orthopaedic Residents' Conference, Memphis, TN, August 1995.

Kim D, Patel AI, Brown W, Friermood TG: Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome. Barnard Competition, Denver, CO, Mar 1995, Scoliosis Research Society, Asheville, NC, Sep 95.

Kim D, Patel AI, Brown W, Friermood TG: Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome. Academy of Surgical Research, Albuquerque, NM, October 1995.

Kim D, Patel A, Brown C, Friermood TG, Wagner JK: Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome. 8th Annual AOA Zimmer Annual Travel Awards Competition for Orthopaedic Residents. White Sulphur Springs, WV, March 1995.

Kim D, Patel A, Brown C, Friermood TG, Wagner JK: Arthrodesis of the sacroiliac joint for sacroiliac joint syndrome. Preliminary Review of Results. Denver, CO October 1995.

*Lisecki E, Samson MM: Randomized, prospective clinical evaluation of hydroxyapatite coated and non-coated porous total hip replacements by a single surgeon. Orlando, FL, Feb 95, Am Acad Ortho Surg.

*Lisecki E, Callahan B, Wolff J, Banks R, Cook S, Samson M: Factors affecting bone ingrowth. 1995 Reconstructive Surgery of the Hip and Knee Course. Telluride, CO, March 1995.

Lisecki EJ: Osteolysis. 1995 Reconstructive Surgery of the Hip and Knee Course, Telluride, CO, March 1995.

*Lisecki EJ, Sherman RA, Harrington LE, Corcoran KD: Development of a percutaneous limb prosthetic holder in a goat model. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

*Lisecki E, Callahan B, Wolff J, Banks R, Cook S, Samson MM: Factors affecting bone ingrowth. SOMOS, Hilton Head, SC Nov 94

Lisecki EJ, Johnson WA, Callahan JJ, Gillogly SD, Berrey BH: Hip lesions mimicking primary osteoarthritis: A radiographic and histopathologic study. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

Lisecki EJ: Osteolysis. 4th Annual Hips and Chips, Parker, CO August 1995.

*Lisecki E, Clyde M: Randomized, prospective comparison of three mechanical compressive devices in total joint arthroplasty. Vail, CO, Jan 95, NuTech 1995 Medical Symposium on DVT Prophylaxis, Edema Reduction & Enhanced Wound Healing

*McBride JT, Piatt BE, Grey SG, Rodkey WG, Gersoff WK: Evaluation of the repeat harvest of the central one-third of the patellar tendon in a goat model. Vail, CO, December, 1995.

*McBride J, Kim D, Stoneman P, Meade W: The effect of furosemide on swelling in the acutely sprained ankle. Orlando, FL, Feb 95, Am Acad Ortho Surg.

*McBride J, Kim D, Stoneman D, Meade W: The effect of furosemide on swelling in the acutely sprained ankle. Vail, CO 8-10 Dec 94 Steadman-Hawkins Fellows Mtg

*McBride T: The effect of furosemide on swelling in the acutely sprained ankle Orlando, FL Feb 95 Am Acad Ortho Surg.

*McBride T, Kim D, Stoneman D, Meade W: The effect of furosemide on swelling in the acutely sprained ankle. Hilton Head, SC, November 1994.

Nelson B, Lisecki E, Callahan J, Gillogly S, Berrey BH: Hip lesions mimicking primary osteo arthritis: A radiographic and histopathologic study Orlando, FL, Feb 95, Am Acad Ortho Surg.

Nelson BJ, Chow G: Functional outcome of thoracolumbar burst fractures treated with hyperextension casting or bracing and early mobilization. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

Nelson, BJ, Chow G: Functional outcome of thoracolumbar burst fractures treated with hyperextension casting or bracing and early mobilization. Barnard Competition, Denver, CO, March 1995.

*Pace WT, Harrington LE, Place HM: Accuracy of medical electronic databases for research. Society of Military Orthopaedic Surgeons, Vail, CO, December 1995.

*Pace WT, Harrington LE, Place H: Accuracy of military electronic databases for research. Denver, CO, March 1995.

*Pace WT, Harrington LE, Place H: Accuracy of electronic medical databases for research. North American Spine Society, 10th Annual Meeting, Washington, DC, October 1995.

*Pace WT, Harrington LE, Place HM: Accuracy of medical electronic databases for research. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1995.

*Peterson B, Jones, DEC, Sherman R: Pulsed electromagnetic fields as therapy for treatment of tibial and metatarsal stress fractures. Orlando, FL, Feb 95. Am Acad Ortho Surg

*Place HM, Enzenauer R, Muff B, Ziporin P: Hypomagnesemia in postoperative spine fusion patients. North American Spine Society, 10th Annual Meeting, Washington, DC, October 1995.

*Place HM, Enzenauer R, Muff B: Hypomagnesemia in postoperative spine fusion patients. North American Spine Society, 10th Annual Meeting, Washington, DC, October, 1995.

*Place H, Pace WT, Harrington LE: Accuracy of military electronic databases for research. Academy of Surgical Research, Albuquerque, NM, October 1995.

*Place H, Pace WT, Harrington LE: Accuracy of military electronic databases for research. Barnard Competition, Denver, CO, Mar 1995.

*Reister JA, Kim D, Lisecki EJ: Bipolar versus unipolar hemiarthroplasty: A comparison of in vitro stability. Barnard Competition, Denver, CO, March 1995.

*Reister JA, Kim DH, Lisecki EJ: Bipolar versus unipolar hemiarthroplasty: A comparison of in vitro stability. Society of Military Orthopaedic Surgeons, Vail, CO, December, 1995.

*Reister J, Jones DEC, Rak K: Carpal ligamentous injuries associated with fractures of the distal radius SOMOS Hilton Head, SC 13-18 NOV 94

*Topper SM, Wood MB, Ruby LK: Ulnar styloid abutment syndrome. American Academy of Orthopaedic Surgeons, Atlanta, GA, February 1996.

*Topper SM, Wood MB, Ruby LK: Ulnar styloid abutment syndrome. Dayton, OH, 23-27 Apr 95.

*Topper SM, Smith DK: MRI of the humpback scaphoid. Helsinki, Finland, July 1995.

*Topper SM, Wood MB, Ruby LK: Ulnar styloid abutment syndrome. Helsinki, Finland, July 1995.

*Topper SM, Wood MB: Ulnar styloid abutment syndrome. Vail, CO, December 1995.

*Topper S, Wood M, Ruby L: Ulnar styloid abutment syndrome. American Society for Surgery of the Hand, San Francisco, CA, September 1995.

*Wood MB, et al: Ulnar styloid abutment syndrome. Vail, CO, December 1995.

PUBLICATIONS - FY95

*** = Protocol Related**

Deputy Commander

Zaloznik AJ: Cancer in active duty women. ASCO Proceedings, December 1995.

Zaloznik AJ: So little time. The Pharos, March 1995.

Zaloznik AJ: Breast cancer stage at diagnosis: Caucasians versus Hispanics. Breast Cancer Research & Treatment, July 1995.

Department of Clinical Investigation

Harrison SM Harris RW, Bales JD: Attempt to correlate urine arsenic excretion with clinical course during melarsoprol therapy of patients with Rhodesian Trypanosomiasis. J Clin Invest, January 1995.

Lieberman M: Determination of neutrophil activation by chemiluminescence using the Packard topcount system. Packard TopClunt Topics, January 1995.

Department of Medicine

Allergy/Immunology Service

*Katial RK, Lieberman M, Muehlbauer SL, Hamilos D: T-lymphocytosis associated with common variable immunodeficiency. Submitted, J Clin Immunol, November 1995.

Cardiology Service

Culclasure TF, Dorogy ME, Enzenauer RJ: Cryoglobulinemia: A reversible cause of dilated cardiomyopathy. Am J Card, (case report section), March 1995.

Dermatology Service

David-Bajar, KM: Photosensitive Dermatitis. Secrets in Dermatology, May 1995.

David-Bajar, KM: Cutaneous manifestations of renal disease. Secrets in Dermatology, May 1995.

David-Bajar, KM: Collagen vascular diseases. Secrets in Dermatology, May 1995.

Fitzpatrick JE, Gentry RH, Williams W: Cutaneous manifestations of African Trypanosomiasis. Arch Dermatol, May, 1995.

Fitzpatrick JE: Syphilis. Dermatology Secrets, May 1995.

*Grammar-West NY, Fitzpatrick JE, Jackson RL, Horton H, Damiano MA: Comparison testing of the irritancy of hand dishwashing liquids using modified patch testing methods. The J Am Acad Dermatol, December 1995.

McGovern TW, Erickson AR, Fitzpatrick JE: Sjogren's syndrome plasma cell panniculitis and hidradenitis. J Cutaneous Pathology, Aug, 1995.

McGovern TW, Enzenauer RJ, Fitzpatrick JE: Treatment of recalcitrant leg ulcers in cryoglobulinemia types I and II with plasmapheresis. Arch Derm, Aug, 1995.

McGovern, TW: Dermatitis (eczema). Dermatology Secrets, May 1995.

McGovern, TW: Diffuse blisters and erosions in a patient with scleroderma. Archives of Dermatology, May 1995.

Richey T: Granulomatous diseases of the skin. Secrets of Dermatology, May 1995.

Endocrine Service

McDermott MT, Georgitis WJ: Adrenal crisis in active duty service members. Military Medicine, December 1995.

Rensch MJ, Merenich JA, Lieberman M, Long BD, Davis DR, McNally PR: Gluten sensitive enteropathy in patients with insulin dependent diabetes mellitus. Ann Int Med, Accepted for publication 1995.

Simic KJ, Georgitis WJ, McDermott MT: Cushing's disease, pituitary apoplexy, and minnie G. Ann Int Med, February 1995.

Infectious Disease Service

*Skillman DR, Malone JL, Decker CF, Wagner KF, Mapou RL, Liao MJ, Testa D, Meltzer MS: Phase I trial of interferon alfa-n3 in early stage HIV-1 disease: Evidence of drug safety, tolerance and antiviral activity. Ann Int Med, April, 1995.

Pulmonary Disease Service

Caras WE, Pluss, JL: Chronic necrotizing pulmonary aspergillosis pathological outcome with itraconazole. Chest, January 1995.

DePriest J: Which ICU patients require ulcer prophylaxis, and with what? Postgraduate Medicine, August 1995.

DePriest J: Low incidence of hemodynamic instability in patients with gastrointestinal hemorrhage. Southern Med J, August 1995.

*DePriest J: Can venous oximetry help confirm proper pulmonary artery catheter placement? Chest, August, 1995.

Enzenauer RJ, Pluss JL: Septic olecranon bursitis in COPD patients. Am J Med, December 1995.

Kristo DA, Turner JF, Hugler R: Transtracheal oxygen catheterization with pneumomediastinum and sudden death. Chest, February 1995.

Rheumatology Service

Erickson AR, Yeun JY, Reddy V, Vogelgesang SA, West SG: Usefulness of the American College of Rheumatology recommendations for liver biopsy in methotrexate-treated patients with rheumatoid arthritis. Arthritis and Rheumatism, November 1994.

Erickson AR, Yeun JY, Enzenauer RJ: Chronic calcium pyrophosphate deposition disease arthropathy associated with hypomagnesemia. Arthritis and Rheumatism, September 1995.

*May K, Mercill D, McDermott MT, West SG: The effect of methotrexate on mouse bone cells in culture. Arthritis and Rheumatism, December 1995.

*Perloff JJ, West S, McDermott MT, Rubin RL: Autoantibodies in lovastatin-treated patients. Arth & Rheum, March 1995.

Singleton JD, West SG, Reddy V, Rak K: Cerebral vasculitis complicating rheumatoid arthritis. So Med J. November 1994.

Department of Nursing

Simic KJ, et al: Cushing's disease, pituitary apoplexy, and minnie G. Ann Int Med, February 1995.

Department of Pediatrics

Burgess D: Development and growth. Handbook of Pediatrics, 18th Edition, Appleton and Lange, 1995.

*Whittler RR, Lieberman MM, Paine DD, Muehlbauer SL, Lima JE, Sachanandani DM, Pinney CA: Effects of interferon-gamma on rat neonatal and adult polymorphonuclear leukocytes; chemiluminescent and flow cytometric analysis. Submitted October 1995, J Inf Dis.

Department of Radiology

Eng TY, Kimball S, Stack R: Seminoma: Does lymph angiogram make a difference ? An analysis of patients treated over the past 15 years. Int J Rad/Oncol/Biol Phys, May 1995.

McBiles M, Lambert AT, Cote MG, Solano RK: Diuretic scintigraphy: Past, present and future. Annual Nuclear Medicine, 1995.

McBiles M, Lambert AT, Cote MG, Kim SY: Sestamibi parathyroid imaging. Seminars in Nuc Med, February 1995.

Lambert AT, McBiles, M: First impressions. J Nuc Med, April 1995.

Lambert AT, McBiles M, Humulock K, Tell DT: In-111 pentetreotide accumulation in a teratoma: A case report. Clin Nucl Med, February 1995.

Lambert AT, McBiles M: False positive indium-111 pentetreotide uptake due to a recent cerebral infarct. J Nuc Med, May 1995.

Lambert AT, McBiles M ; Chronic recurrent multifocal osteomyelitis. J Nuc Med, May 1995.

Department of Surgery

Audiology Service

Ferrer-Vincent ST: Audiologic findings in one case of dolichoectatic basilar artery (a case report) Am Auditory Society Bulletin, February 1995.

Orthopedic Service

*Castello P, McBride J, Hockenbury RT, Gillogly SD, Corcoran K: A comparison of patellar graft fixation technique in anterior cruciate ligament reconstruction using a goat model. Orthopedic Trans, February 1995.

*Clyde M, Nelson B, Lisecki E: The comparison of three pneumatic compression devices for the prevention of deep venous thrombosis in total joint replacement patients: A prospective randomized study. NuTech CO, April 1995.

*Friedel SP, Lisecki EJ, Samson MM: A comparison of three devices used for autologous blood transfusion following total joint replacement: A prospective, randomized study. The J of Arthroplasty, 1995; Orthopedic Transactions, November, 1994.

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- (1) Date: 5 Sep 95 (2) Protocol #: 81/117 (3) Status: Completed
- (4) Title: The Role of Calcitonin in Osteoporosis
- (5) Start Date: Reactivate 1987 (6) Est Compl Date:
- (7) Principal Investigator: Michael T. McDermott, COL, MC (8) Facility: FAMC
- (9) Dept/Svc: MED/Endocrine (10) Associate Investigators:
- (11) Key Words:
osteoporosis
bone density
calcitonin deficiency
thyroid hormone
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 243
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, lose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and than normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - calcitonin deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal controls. (SPA) single photon absorptiometry-distal and midradius serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip- cross-sectionally.

(17) Progress: Data collection is complete. Longitudinal bone mass changes have been calculated as the slope of the lines depicting adjusted bone mass values over time.

Consistent with our original hypotheses bone loss was fastest in the cancer group which also had the highest synthroid doses of T4 levels. Bone loss was next fastest in the goiter group and slowest in the controls. These differences were all statistically significant at the spine, hip and forearm. Analysis of ancillary demographic data is in progress and a manuscript is in preparation.

FY94: Analysis of ancillary demographic data is complete, and the manuscript was submitted for publication. FY95: Manuscript recently published.

Publications:

McDermott MT, Kidd GS, Blue P, Ghaed V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res (1(suppl. 1):352, 1986 (Abstract).

McDermott MT, Perloff JJ, Kidd GS: A Longitudinal Assessment of Bone Loss in Women with Levothyroxine Suppressed Benign Thyroid Disease and thyroid Cancer. Calcif Tissue Int 56:521-5, 1995.

Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.

Perloff JJ, McDermott MT, Damiano MA, Kidd GS: The effects of thyroid hormone suppression and calcitonin deficiency on bone mass. 74th meeting of the Endocrine Society, San Antonio, TX, June 1992.

Detail Summary Sheet

(1) Date: 1 Nov 94 (2) Protocol #: 81/118 (3) Status: Terminated

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Michael T. McDermott, COL, MC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:
Gerald S. Kidd, COL, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis
gonadotropins, pituitary

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV__ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date: 1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing,
clinical stimulation and HCG testing in males and females.

(17) Progress: No progress in the past three years.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Nov 94 (2) Protocol #: 83/126 (3) Status: Terminated

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired
Water Excretion and Abnormal Renin-Aldosterone Axis of
Hypothyroidism

(5) Start Date: 1983 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael McDermott, COL, MC

(9) Dept/Svc: MED/ Endocrine (10) Associate Investigators:
Gerald Kidd, COL, MC

(11) Key Words:
prostaglandin synthetic
hypothyroidism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and
designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: Because of funding problems, we are asking the University of Colorado to measure ADH levels, and as soon as they agree, the study will begin. No progress in FY94,

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 Jan 95 (2) Protocol #: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HIV 1 Infection and Disease in a
United States Military Community

(5) Start Date: 1986

(6) Est Compl Date: 1996

(7) Principal Investigator:
Wheaton Williams, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators
Richard Harris, LTC, MS
Jefferey Casserly, PA-C

(11) Key Words:
HIV virus

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan

b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting
Period: _____

d. Total Number of Subjects Enrolled to Date: 670

e. Note any adverse drug reactions reported to the FDA or sponsor
for studying under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough
understanding of the pattern of disease progression and clinical
course in individuals with documented HIV infection within the
general military population including active duty, dependents,
and retirees. This will provide critical information for
clinical and administrative management of patients.

(16) Technical Approach: Collect data on all patients who are
required to be staged by DA directives and any who request
staging.

(17) Progress: Continuing to enroll newly diagnosed HIV patients.

Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: 1 Aug 95 (2) Protocol #: 88/115 (3) Status: Terminated
-
- (4) Title: The Impact of an Ambulatory Care Rotation on Interns
Psychosocial Attitudes
-
- (5) Start Date: 1989 (6) Est Compl Date: 1998
-
- (7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 50-60
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.
- (16) Technical Approach: Each intern who does a one month ambulatory care rotation in the internal medicine clinic is given a cognitive knowledge test and a psychosocial attitudes questionnaire at the beginning of the rotation, and again at the end of the rotation.
- (17) Progress: Two years of questionnaires have been administered to interns who are now junior and senior residents. Protocol was amended in May 92 to extend the study up to 6 years, administering the same questionnaire to these residents to determine the long-term changes in attitude through training and into their first years of practice or subspecialty training. FY94: Average 8 interns per year enrolled in this study. FY95: Terminated due to retirement of PI.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 1 Aug 95 (2) Protocol #: 88/121 (3) Status: Ongoing

(4) Title: Bone Densitometry in Thyroid Extract Treated Patients

(5) Start Date: 1988 (6) Est Compl Date: 1995

(7) Principal Investigator: William J. Georgitis, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 30 controls
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether thyroid extract has greater adverse effects on bone density and calcium metabolism than synthetic l-thyroxine. The second is to assess the reversibility of any documented effect.

(16) Technical Approach: The effects of thyroid extract treatment on bone densitometry will be investigated. Subjects taking thyroid extract treatment matched with a thyroxine controlled group will have assessments of thyroid replacement therapy status, mineral metabolism and bone density. Thyroid extract subjects found to be subclinically hyperthyroid may enter a longitudinal assessment of bone density after crossing over to euthyroid thyroxine replacement.

(17) Progress: FY94: Subclinically hyperthyroid patients changed from thyroid extract to l-thyroxine continue to have annual BMD determinations (n=7). FY95: Continuing serial followup.

Publications and Presentations:

1. Georgitis WJ, Abrams LF, Dolbow A, Bunker DM: Bone densitometry in patients taking thyroid extract. Presented: American Society for Bone and Mineral Research/International Conference on Calcium-regulating Hormones. 1st Joint Meeting. Abstract 219:S172, Montreal, Quebec, September 1989.

2. Abrams L, Georgitis W, Dolbow A, Bunker D, Kidd G: Is anyone taking thyroid extract consistently euthyroid? The Endocrine Society, 72nd Meeting, Atlanta, GA, 1990.

Detail Summary Sheet

- (1) Date: 1 Nov 94 (2) Protocol #: 89/102 (3) Status: Terminated
- (4) Title: Factors Determining Peak Bone Mass and Subsequent Bone Loss
- (5) Start Date: (6) Est Compl Date:
- (7) Principal Investigator: Michael T. McDermott, COL, MC (8) Facility: FAMC
- (9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:
- (11) Key Words:
bone density
peak bone mass
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
- (14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
- (15) Study Objective: To determine factors associated with the development of peak bone mass and subsequent bone loss.
- (16) Technical Approach: Bone density of the radius (single photon absorptiometry) and of the hip and spine (dual photon absorptiometry) will be done in a large group of male and female volunteers, who will also, on another protocol, be having total body fat and lean mass measured by dual photo absorptiometry. Questionnaire concerning present and past calcium intake, exercise and other habits will also be administered.
- (17) Progress: No progress to date.
- Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Nov 94 (2) Protocol #: 89/105 (3) Status: Ongoing

(4) Title: Appropriate Blood Pressure Control in Diabetes Trial
Protocol (ABCD Trial)

(5) Start Date: 1991 (6) Est Compl Date: 1998

(7) Principal Investigator: Michael McDermott, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:
nephropathy
diabetes

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 52
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" To date no serious adverse events by FAMC patients thought to be secondary to study involvement.

((15) Study Objective: a) Define a level of blood pressure control in a prospective, randomized, non-blinded fashion needed to prevent or delay the progression of diabetic nephropathy and other microvascular complications of diabetes; b) determine if there is a specific advantage to either a CEI or a Ca++ channel blocker as a mode of treatment for hypertension in regard to the onset or progression of diabetic nephropathy.

(16) Technical Approach: See protocol.

(17) Progress: Approximately 52 Fitzsimons Army Medical Center patients have been enrolled in the protocol without complications. Apparently city-wide approximately 800 patients have agreed to participate, and several hundred are actively involved.
FY95: Blood pressure monitoring continues.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 Jan 95 (2) Protocol #: 89/108 (3) Status: Completed

(4) Title: Efficacy of Pentoxifylline in Treating Diabetic
Impotence

(5) Start Date: 1989 (6) Est Compl Date: 1995

(7) Principal Investigator: William Georgitis, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:
diabetes
impotence
pentoxifylline

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 60
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if pentoxifylline is more effective
than placebo in improving sexual function in non-insulin dependent
diabetic men.

(16) Technical Approach: A single center, double-blind, placebo
controlled study to examine the efficacy of pentoxifylline in improving
sexual function in impotent NIDDM men. Diabetic men with impotence who
meet the protocol entrance criteria will be randomly assigned placebo or
pentoxifylline for 12 weeks. After completion of the treatment course
subjects will be reevaluated, and groups will be compared to determine
beneficial effects.

(17) Progress: Data collection phase complete. All volunteers have
finished medication as of 1 Oct 92. We are now in data synthesis phase.
FY94: A manuscript is in the preparation phase, and an abstract was
presented at a national meeting.

Publications and Presentations: Accepted 3 Oct 94 for publication in
Diabetes Care: Georgitis WJ, Merenich, JA, Trial of Pentoxifylline for
diabetic Impotence.

Detail Summary Sheet

-
- (1) Date: 5 Sep 95 (2) Protocol #: 90/100 (3) Status: Ongoing
-
- (4) Title: Platelet Thromboxane and Aggregation and Whole Blood
Prostacyclin Synthesis in Human Thyroid Disease
-
- (5) Start Date: 1990 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Reed Christensen, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Endocrinology (10) Associate Investigators:
Michael T. McDermott, LTC, MC
(11) Key Words: Sharon Noble, DAC
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Oct b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine the roles of thromboxane and
prostacyclin in mediating the phenomenon associated with thyroid
dysfunction.
- (16) Technical Approach: See protocol.
- (17) Progress: As of this date pre- and post- data have been completed
on 25 patients. Need about 35 more patients to complete the study. No
complications. Laboratory methods and analysis are progressing well.
New investigators have been added to the study. FY95: No progress.

Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: 7 Mar 95 (2) Protocol #: 90/112 (3) Status: Completed
-
- (4) Title: Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM)
-
- (5) Start Date: 1990 (6) Est Compl Date: 1994
-
- (7) Principal Investigator: Michael McDermott, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Endocrine (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: MARCH b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 240
d. Total Number of Subjects Enrolled to Date: 800
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To provide a systemic means for all NIDDM patients at FAMC to be screened and to make physicians aware of the need for this intervention.
- (16) Technical Approach: See protocol.
- (17) Progress: Finished data collection, expect paper to be written in Fall 1994.
- Publications and Presentations: None

Detail Summary Sheet

- (1) Date: 4 Apr 95 (2) Protocol #: 90/117 (3) Status: Ongoing
- (4) Title: The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions
- (5) Start Date: 1990 (6) Est Compl Date: Jun 96
- (7) Principal Investigator: Arnold Asp, LTC, MC (8) Facility: FAMC
- (9) Dept/Svc: Endocrine (10) Associate Investigators: Michael McDermott, COL, MC
William Georgitis, COL, MC
Mark Larson, LTC, MC
- (11) Key Words: thyroid
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
- (14) a. Date, Latest IRC Review: APRIL b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
- (15) Study Objective: To determine if suppressive doses of levothyroxine (documented by an 'ultrasensitive' TSH assay) reduces the size (by ultrasound) of newly discovered, biopsy "non-malignant" thyroid nodules; if response to suppression therapy differs between patients with truly uninodular lesions VS those in whom ultrasound examination uncovers the presence of multiple nodules; if any FNA cytologic changes occur after a course of suppression therapy and the utility of serum thyroglobulin as a biochemical marker of changes in nodular size or cytology.
- (16) Technical Approach: See protocol.
- (17) Progress: Began recruiting patients Summer, 1992. Thirteen patients enrolled to date. No complication or problems. FY95: Four additional subjects enrolled.

Publications and Presentations: None

Detail Summary Sheet

- (1) Date: 11 Jul 95 (2) Protocol #: 90/132 (3) Status: Ongoing
- (4) Title: Prevention and Treatment of Steroid Induced Osteoporosis
- (5) Start Date: 1990 (6) Est Compl Date: 1996
- (7) Principal Investigator: Michael McDermott, COL, MC (8) Facility: FAMC
- (9) Dept/Svc: MED/Endocrine (10) Associate Investigators:
John Merenich, MAJ, MC
William Georgitis, LTC, MC
James Singleton, MAJ, MC
Sterling West, LTC, MC
Nadine Alex, CPT, MC
- (11) Key Words:
osteoporosis
steroids
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
- (14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
- (15) Study Objective: Prevention and treatment of steroid induced osteoporosis.
- (16) Technical Approach: Randomized controlled prospective single blind evaluation of the efficacy of a coherence therapy regimen in the prevention and treatment of steroid induced osteoporosis.
- (17) Progress: Patients are being studied with more undergoing enrollment. Five patients have withdrawn for personal reasons. FY94: Four subjects enrolled this report period for a total of 28. Total of 15 patients have withdrawn for personal health or reassignment/relocation reasons. No drug reactions thus far. This leaves a total of 13 patients ; 4 have completed the study and 11 are ongoing study subjects. FY95: Study is ongoing but 12-month and 24-month data on some patients will be presented at the Endocrine Society meeting in Washington, DC, in June 1995.
- Publications and Presentations: As above.

Detail Summary Sheet

-
- (1) Date: 1 Nov 94 (2) Protocol #: 91/106 (3) Status: Ongoing
-
- (4) Title: A Randomized, Controlled Trial of Interferon Alpha and Thymosin Alpha-1 in Patients with Hepatitis C Antibody Positive Chronic Active Hepatitis
-
- (5) Start Date: 1991 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Dirk Davis, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Gastroenterology (10) Associate Investigators:
-
- (11) Key Words: Zachary Goodman, MD, PhD
hepatitis Kamal Ishak, MD, PhD
interferon alpha Kenneth Sherman, MD
thymosin alpha-1
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 18
d. Total Number of Subjects Enrolled to Date: 70
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Demonstrate efficacy of recombinant interferon alpha 2b among military personnel and those eligible for care under the auspices of DOD for treatment of chronic hepatitis C. Attempt to augment the response to interferon using Thymosin alpha-1 as in a immunomodulator.
-
- (16) Technical Approach: Randomized, three-arm study: 1) treatment with interferon alpha + placebo; 2) interferon alpha + thymosin alpha-1; and 3) placebo (controls). Six-month study cycles with 40 adult chronic hepatitis C patients per arm.
-
- (17) Progress: To date 56 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. There have been no serious adverse events associated with drug therapy. One patient was dropped due to evidence of non-compliance. One patient missed several key visits and was dropped. One patient decided to discontinue participation at 12 weeks. WRAMC enrolled five additional patients for a total of 9. Preliminary analysis shows evidence of IFA/TA-1 response.

Progress FY95: To date 70 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. One patient was dropped due to evidence of non-compliance. One patient decided to discontinue participation at 12 weeks. One patient decided to drop due to a new truck driving position which would not allow traveling with syringes. WRAMC has enrolled a total of 15 patients. Preliminary analysis shows evidence of IFA/TA-1 response.

(14)e. There have been no serious adverse events associated with drug therapy. One serious adverse event for FY 1994 has occurred. Pt #135 had elbow pain present for approximately 1.5 years, which existed prior to starting therapy. During week 19 of therapy, he had an elective same day surgery procedure---a lateral release of the left elbow.

Publications: Sherman KE, et al: Thymosin Alpha-1 and circulating T-cell subsets in patients with chronic hepatitis C virus infection. Hepatology, vol 18, no 4, Oct 93.

Sherman KE, et al: Thymosin Alpha-1 and circulating T-cell subsets in patients with chronic hepatitis C virus infection. Hepatology, supplement Oct 94, abstract #444.

Presentations: American Association for the study of liver diseases, National Meeting in Chicago, Nov 14, 94.

Detail Summary Sheet

-
- (1) Date: 1 Nov 94 (2) Protocol #: 91/107 (3) Status: Ongoing
-
- (4) Title: Does Omeprazole (Losec*) Improve Respiratory Function in Asthma Patients with Gastroesophageal Reflux? A Double-Blind, Crossover Study
-
- (5) Start Date: 1991 (6) Est Compl Date:
-
- (7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Gastroenterology (10) Associate Investigators: Michael Fisher, MAJ, MC MC
Nancy Stocker, Phar.D.
-
- (11) Key Words:
GI reflux
omeprazole
asthma
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: __Nov__ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: __1__
d. Total Number of Subjects Enrolled to Date: __36__
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: The purpose of this study is to determine whether asthmatic patients with GER will experience improved respiratory function when GER is treated with omeprazole.
- (16) Technical Approach: Patients will be randomized to drug or placebo and evaluated by a number of tests to include gastrointestinal investigation to evaluate for GER, intermittent pulmonary function testing, blood tests, esophageal manometry, Bernstein test, 24=hr. esophageal pH monitoring and EGD.
- (17) Progress: To date 35 patients enrolled. Preliminary data: 25% of asthma patients with GERD show objective improvement in PFT's when GERD treated with Omeprazole. FY94: Enrollment continues. Amendment "An Open Label Dose Ranging Extension Study to Evaluate the Efficacy of Omeprazole for 12 Weeks in Asthma Patients with Gastroesophageal Reflux" was added in Mar 94. FY95: One new subject. Enrollment sluggish due to change in staff and loss of Allergy Fellowship.
- Presentations: Preliminary data presented: Dig. Dis. Week, April 1992; Follow-up presented Am. Coll Gastro, October 1992.

Detail Summary Sheet

- (1) Date: 5 Sep 95 (2) Protocol #: 91/113 (3) Status: Ongoing
-
- (4) Title: The Effect of Recombinant Growth Hormone on Pulmonary Function in Patients with Chronic Obstructive Pulmonary Disease
-
- (5) Start Date: 1991 (6) Est Compl Date: 1994
-
- (7) Principal Investigator: Michael McDermott, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Endocrinology (10) Associate Investigators:
-
- (11) Key Words: growth hormone COPD Michael McCormack, CPT, MC
Marin Kollef, MAJ, MC
William Georgitis, LTC, MC
John Merenich, MAJ, MC
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Dec b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" No adverse reactions
-
- (15) Study Objective: To test the effect of recombinant growth hormone on breathing ability.
-
- (16) Technical Approach: Randomized, prospective, double-blind, placebo-controlled design using recombinant human growth hormone or sterile saline placebo in patients with severe chronic obstructive pulmonary disease currently under follow-up in the Pulmonary Clinic at FAMC. Patients will be treated for one year.
-
- (17) Progress: Fifteen patients were recruited. Six have dropped out for various reasons; inconvenience, intermittent illness and being "tired of taking shots" were the most common reasons. No one dropped out due to side effects. Six have completed one year, have had their final studies and are now off treatment. Three are from 3-7 months into the study and are doing well. Data collected thus far has not been analyzed as we remain blinded as to their treatment until the study's end. FY94: Eight patients completed the study. Seven dropped out for a variety of reasons, non related to the medications. There was one death but he was found to be in the placebo group. Final data is currently being analyzed. FY95: Manuscript in preparation.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 91/114 (3) Status: Terminated

(4) Title: Detection of Renal Artery Stenosis by Noninvasive Testing

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Jane Yeun, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology (10) Associate Investigators:

(11) Key Words:
renal artery stenosis
captopril
enalaprilat
renogram

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the specificity and sensitivity of Captopril challenge, Captopril renogram, Enalaprilat renogram, and duplex ultrasonography in the diagnosis of RAS compared to the standard arteriography.

(16) Technical Approach: All patients studies will undergo captopril challenge, captopril renogram, enalaprilat renogram, duplex ultrasonography and renal arteriogram. Power analysis will be conducted to determine requirements for total number of patients after first 20 enrolled.

(17) Progress: No progress this FY. Patient enrollment slower than anticipated. Data collection only to this point. FY94: No progress since FY93 Annual Progress Report. FY95: No progress. With continued decrease in patient population and closure eminent, will not be able to complete study by projected DCI deadline of 6/96.

Publications and Presentations: None.

Detail Summary Sheet

- (1) Date: 3 Jan 95 (2) Protocol #: 91/122 (3) Status: Completed
- (4) Title: A Multicenter, Double-Blind Study to Evaluate the Safety and Therapeutic Efficacy of Omeprazole 20mg A.M. or 10mg A.M. as Compared to Placebo During 12/24 Months Maintenance Treatment of Patients with Duodenal Ulcer Healing Following 4 Weeks of Omeprazole 20mg A.M.
- (5) Start Date: 1991 (6) Est Compl Date: 1995
- (7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC
- (9) Dept/Svc: Gastroenterology (10) Associate Investigators: John Meier, MAJ, MC
Robert Sudduth, MAJ, MC
Nancy Stocker, Pharm.D.
- (11) Key Words: omeprazole
duodenal ulcer
investigational new drug
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
- (14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
- (15) Study Objective: The purpose of this investigational new drug study is to determine if patients identified to have a duodenal ulcer that is healed with omeprazole can be prevented from experiencing an ulcer relapse when given on of two dosages or concentrations of this medicine when compared to a placebo.
- (16) Technical Approach: After endoscopy verifies ulcer healing with omeprazole, patients will be randomized to receive either maintenance treatment with omeprazole (10 mg or 20 mg each morning) or placebo. Laboratory tests and EGD will be performed.
- (17) Progress: Twelve patients have been enrolled to date. Eight entered the maintenance phase, two have elected not to participate in the 2nd year of maintenance and one had recurrent PUD in the 2nd year. No significant AEs.
- FY94: No new subjects enrolled this report period because enrollment is closed. Subjects are completing the maintenance phase. Anticipate completion of the study sometime in Jan 94 with data analysis to follow.
FY95: No progress. Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Feb 95 (2) Protocol #: 91/125 (3) Status: Ongoing

(4) Title: An Ultrastructural Study of the Dermal-Epidermal Junction Following Skin Splitting with Various Methods

(5) Start Date: 1991 (6) Est Compl Date: Apr 95

(7) Principal Investigator: Kathleen David-Bajar, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators: Scott Bennion, COL, MC

(11) Key Words: skin splitting SSG Tom Johnson Ron Jackson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate a reproducible site of separation, routine use of such "split skin" methods that will become the standard for the indirect immunofluorescence evaluation of bullous skin disorders.

(16) Technical Approach: Specimens of discarded human adult skin and neonatal foreskin will be subjected to dermal-epidermal separation using each of three methods: NaCl, EDTA, and dispase. Each specimen will then be processed for electron microscopy, after incubation in specific monoclonal antibodies to known anatomic components of the dermal-epidermal junction. Two investigators independently evaluate and be blinded to the source of the specimens in making their assessments.

(17) Progress: For much of the last year we did not have an electromicroscopy technician. A new technician, SSG Johnson is now working on this project and has successfully processed intact neonatal skin. He is learning the split-skin techniques, and will begin working on the immunogold staining as soon as reagents are received.

FY94: Three methods for chemically splitting skin have been tested. Transmission electron microscopy has shown that with 1M NaCl treatment epidermal-dermal splits occur exclusively in the lamina lucida of the basement membrane zone; these results are consistent with expected hypotheses. Work continues on developing immunogold labeling for specific antigen staining of basement membrane components.

Continuation - DETAIL SUMMARY SHEET 91/125

FY95: Recently our electron microscopy technician, SSG Johnson, has successfully performed immunogold staining, using the monoclonal antibodies described for this protocol. Additional specimens are being processed to confirm the initial results. When three specimens have been processed for each of the conditions described, with each of the monoclonal antibodies being studied, the project will be completed. It is anticipated this will be accomplished by April 1995. An abstract describing the results obtained thus far has been accepted for presentation at the Western Society for Investigative Dermatology Meeting in Feb 95.

Publications and Presentations: As above.

Detail Summary Sheet

-
- (1) Date: 6 Jun 95 (2) Protocol #: 91/134 (3) Status: Ongoing
-
- (4) Title: The Use of Cultured Skin Cells and Monoclonal Antibodies to Evaluate the Development and Function of Various Proteins in Keratinocytes and Other Epidermal and Dermal Cells
-
- (5) Start Date: 1991 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Scott Bennion, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Dermatology (10) Associate Investigators:
James Fitzpatrick, LTC, MC
Loren Golitz, MD, UCHSC
Ron Jackson, PhD
-
- (11) Key Words:
keratinocytes
monoclonal antibodies
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Through the use of cultured human epidermal cells this study will determine the specificity of monoclonal antibodies for certain skin protein antigens implicated in skin tumors and whether the expression of these antigens changes with alterations in the cell culture environment such as density of cells and exposure to UV light.
- (16) Technical Approach: This study involves a number of highly technical laboratory procedures as outlined in the protocol.
- (17) Progress: Continue to evaluate staining methods to determine the optimal staining procedures for the cultured human keratinocytes (HKs) with vimentin and cytokeratin. In addition we are also planning to alter the calcium concentrations of the cultures to alter the HK differentiation. We feel that the differentiation of the HKs may play an important part in the expression of both cytokeratin and vimentin. FY94: No progress since FY93 annual progress report. FY95: Continuing to look at HKs for intermediate filament expression. Additionally we are evaluating the monoclonal antibody HMB-45 in nevus/HK cell culture.
- Publications and Presentations: None.

Detail Summary Sheet

-
- (1) Date: 11 Jul 95 (2) Protocol#: 91/136 (3) Status: Completed
-
- (4) Title: I. A Clinical and Radiographic Comparison of Parenteral Gold Versus Parenteral Methotrexate in the Treatment of Early Rheumatoid Arthritis. II. The Effect of Low-Dose Methotrexate on Bone Metabolism and Bone Density
-
- (5) Start Date: 1991 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Sterling West, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Rheumatology (10) Associate Investigators:
Ruth Hugler, RN
Mike McBiles, COL, MC
Michael McDermott, LTC, MC
Paul Miller, MD, UCHSC
Daniel Battafarano, MAJ, MC
-
- (11) Key Words:
arthritis
methotrexate
bone density
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Part I: a) to compare the clinical efficacy of parenteral gold and parenteral methotrexate in the treatment of rheumatoid arthritis; b) to compare radiographic progression of RA in these two treatment groups. Part II: to evaluate the effect of low-dose methotrexate on bone metabolism and bone density.
- (16) Technical Approach: Patients will be randomly assigned to receive either intramuscular methotrexate or gold. Laboratory tests and bone densitometries will be performed periodically to monitor rheumatoid arthritis and drug therapy.
- (17) Progress: Patient accrual continues.
FY94: As of 31 May 94 40 subjects were enrolled, enrollment complete. Subjects are now undergoing serial evaluations including DEXAs. This study will be completed by 31 Dec 94.
FY95: Patient surveys will be completed in Aug 95.
- Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 91/143 (3) Status: Completed

(4) Title: A Multi-Center Randomized Comparative Trial Evaluating Safety and Efficacy of Monopolar Versus Bipolar Polypectomy Snares

(5) Start Date: 1991 (6) Est Compl Date: 1995

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators:
Thomas Kepczyk, MAJ, MC
Scot Lewey, MAJ, MC
Milton Smith, LTC, MC
Dirk Davis, MAJ, MC
Steve Lawrence, MAJ, MC
James Cremins, MAJ, MC

(11) Key Words:
polypectomy
snares

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 294
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare the efficacy, generator settings, and complication rates in the use of the monopolar versus bipolar polypectomy snares for the removal of colonic polyps.

(16) Technical Approach: Large sessile and pedunculated polyps will be lassoed with either the wire snare or the Bi-Snare in a standard fashion. For the Bi-Snare, electrical current will be applied using current settings of CUT 7 wats & COAG 6 with BLEND 2 on FORCE 1B; 1.0 CUT & 1.5 COAG blended-cut on the SSEL2. For the monopolar, electrical current will be applied using standard settings of coagulation 3 and cut 0, at 1 to 2 second pulses.

(17) Progress: Study is ongoing. Interim data analysis showed better results with the Bisnare, but have not reached statistical significance yet. Request one additional year for enrollment.

FY94: Bi-Snare appears to be superior (trend, P non significant). Request permission to continue study n=100, and reanalyze data then (approx. 1 yr). FY95: BiBx useful and safe.

Publications and Presentations: Two presentations and one publication.

Detail Summary Sheet

(1) Date: 4 Oct 94 (2) Protocol #: 92/105 (3) Status: Ongoing

(4) Title: Bi-Bx Removal of "Hard to Reach" Colon Polyps: A
Pilot Evaluation of a New Polypectomy Technique

(5) Start Date: 1992

(6) Est Compl Date: 1995

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro

(10) Associate Investigators
Steve Hammond, MAJ, MC
Sofia DeAngelis, RN

(11) Key Words:
colon polyps
polypectomy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To determine the utility of a new biopsy
technique.

(16) Technical Approach: Prospective evaluation with followup for
technical success and complications.

(17) Progress: Fifty patients enrolled to date, no complications or
untoward side effects. Plan to continue patient enrollment.
Preliminary description of new technique submitted for publication.

Publications: Am J Gastro 87:1329, 1992

Bipolar polypectomy device for removal of colon polyps. PR McNally,
et al. Gastroint Endo 40;1994; 489-91.

Presentations: 2 presentations in FY94. (no details from PI)

Detail Summary Sheet

-
- (1) Date: 1 Nov 94 (2) Protocol #: 92/107 (3) Status: Completed
-
- (4) Title: Treatment of Graves' Disease with Cholestyramine
-
- (5) Start Date: 1992 (6) Est Compl Date: 1993
-
- (7) Principal Investigator: Arnold Asp, LTC, MC (8) Facility: FAMC
-
- (9) Dept of MED/Endocrine (10) Associate Investigators
-
- (11) Key Words: hyperthyroidism cholestyramine Michael McDermott, LTC, MC Gregory B. Hughes, MAJ, MC
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: NOV b. Review Results: c. Number of Subjects Enrolled During Reporting Period: 4 d. Total Number of Subjects Enrolled to Date: 6 e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". **Three patients have developed constipation while taking cholestyramine.**
-
- (15) Study Objective: To evaluate the efficacy of adding cholestyramine to conventional antithyroid drug therapy in rapidly achieving a euthyroid state in patients with active hyperthyroid graves disease.
-
- (16) Technical Approach: Parallel two-group repeated measures design in which half the patients receive traditional therapy with methimazole and atenolol, while the other half receive methimazole and atenolol plus cholestyramine for a period of four weeks.
-
- (17) Progress: Six patients enrolled at FAMC. Seven patients enrolled at WRAMC.

Publications and Presentations: None

Detail Summary Sheet

- (1) Date: 1 Nov 94 (2) Protocol #: 92/109 (3) Status: Ongoing
- (4) Title: Characterization of a Human Thyroid Cancer Cell Line
- (5) Start Date: 1992 (6) Est Compl Date: 1994
- (7) Principal Investigator: William Georgitis, COL, MC (8) Facility: FAMC
- (9) Dept of MED/Endocrine (10) Associate Investigators
- (11) Key Words: cell line thyroid
thyroid cancer Tony Gutierrez
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: NOV____ b. Review Results:____
c. Number of Subjects Enrolled During Reporting Period:____
d. Total Number of Subjects Enrolled to Date:____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: Identify and characterize an immortal thyroid cancer cell line in terms of degree of differentiation and thyroid cell/molecular biology.
- (16) Technical Approach: The cells will be studied using a variety of techniques including immunohisto chemistry, molecular biology and radioisotope methods.
- (17) Progress: Positive immunohistochemical staining for thyroglobulin has been found. Samples of cell culture line have been provided to investigators at other research institutions in the United States.
FY95: No progress.

Presentations:

1. Society of Uniformed Endocrinologists meeting, (poster) June 1992.
2. American Thyroid Association (poster) September 1992.

Detail Summary Sheet

(1) Date: 6 Jun 95 (2) Protocol #: 92/113 (3) Status: Completed

(4) Title: Cyclosporine Treatment of Idiopathic Chronic Active Hepatitis

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: Dirk Davis, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators
Kenneth Sherman, M.D., PhD

(11) Key Words: cyclosporine
hepatitis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec/Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Multicenter trial to evaluate potential for cyclosporin as a therapeutic agent in steroid resistant autoimmune hepatitis.

(16) Technical Approach: Open label therapeutic trial of cyclosporin in patients with idiopathic chronic active hepatitis that is resistant to steroids and/or in patients who cannot tolerate standard immunosuppression methods.

(17) Progress: To date 7 patients with chronic active hepatitis have been enrolled with 4 of these at FAMC. All patients seemed to demonstrate a response. Among patients who completed at least 16 weeks of therapy, 5/7 were classified as responders as defined by normalization or near normalization of ALT. Of this group, two were non-compliant with therapy despite therapeutic responses. One was weaned from cyclosporine and prednisone and remains biochemically normal. One patient at UCHSC died.

Publication: Journal of Hepatology, Dec 94.

Presentations: None

Detail Summary Sheet

-
- (1) Date: 3 Jan 95 (2) Protocol #: 92/116 (3) Status: Ongoing
-
- (4) Title: Early Detection of Second Primary Lung Cancers by Sputum Cytology Immunostaining
-
- (5) Start Date: 1992 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Jerry Pluss, LTC, MC (8) Facility: FAMC
-
- (9) Dept of MED/Pul. Dis. (10) Associate Investigators
-
- (11) Key Words: sputum, immunostaining, cancer
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: Study usefulness of immunostaining cytology compared to regular sputum cytology, cxr and examination in the detection of recurrent lung cancer. This very high risk population is being used instead of cigarette smokers to obtain data on a smaller group of patients in a shorter time frame.
- (16) Technical Approach: Yearly examination of high risk population that develops lung cancer. Using history, physical examination, cxr, induced sputums, non-induced sputums and bronchoscopy to evaluate cytologic methods (routine techniques, immuno staining techniques and other tumor markers).
- (17) Progress: To date 54 patients are registered on this multi-center study with 12 from FAMC. Of the FAMC patients, 3 were found to have recurrent disease, and one patient has moderate atypia. The second year of the study is complete and patients will need to be followed for one more year.
- FY95: To date 71 patients are registered on this multi-center study with 13 from FAMC. Of the FAMC patients, 4 were found to have recurrent disease. There are a few FAMC patients that are still being followed up for their third year of the study. After the data is reviewed by the National Study Group, the study may need to be continued. If so, this request will be submitted to the IRC. Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Feb 95 (2) Protocol #: 92/120 (3) Status: Completed

(4) Title: Prevalence of Gluten Sensitive Enteropathy in Patients
with Insulin Dependent Diabetes Mellitus

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words: celiac disease diabetes
Dr. Davis
Dr. Merenich
Kenneth Sherman, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Prospective evaluation of the prevalence of GSE
among type I IDDM patients.

(16) Technical Approach: Evaluation of the prevalence of GSE among type
I IDDM patients.

(17) Progress: Demographics have been collected on 200 patients and lab
draws done on 100 patients, within 1 week there will be 100 patients
entered.

FY94: 20 pts/20 controls evaluated to date. Enrollment will continue
to approximately 100.

FY95: Three of 47 patients with type I diabetes mellitus were positive
subclinical celiac disease.

Publications: Abstract, Gastro Apr 95.

Presentations: APC, Reston, VA, Oct 94; APC, Colorado Springs, CO, Feb
95; DDW, San Diego, Apr 95.

Detail Summary Sheet

- (1) Date: Sep 95 (2) Protocol #: 92/123 (3) Status: Terminated
- (4) Title: A Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Evaluate the Effect of Quinapril in Reducing Ischemic Events During a 3-Year Follow-up in Patients Post Intervention: QUIET (Quinapril Ischemic Event Trial). (IND) Parke-Davis Protocol 906-370
- (5) Start Date: 1992 (6) Est Compl Date: 1996
- (7) Principal Investigator: Richard Davis, COL, MC (8) Facility: FAMC
- (9) Dept of MED/Cardiology (10) Associate Investigators Robert Cameron, LTC, MC Peter Bigham, MAJ, MC
- (11) Key Words: investigational new drug
ischemia
quinapril
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: MAR/Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". See below.
- (15) Study Objective: To test the effectiveness of an investigational new drug, quinapril, to prevent ischemic events post angioplasty or atherectomy.
- (16) Technical Approach: Multi-center international trial---double-blind, randomized, placebo-controlled. Approximately 75 patients will be enrolled at FAMC and followed for a three-year period.
- (17) Progress: It appears from data gathered at other institutions where subjects have been enrolled for some time that the placebo group requires recatheterization, while treadmills are negative on the active drug group. Enrollment closed 3 Feb 93, patients will be followed for two years.
FY94: Seven of the FAMC patients have discontinued from the study for the following reasons: CABG, pulmonary complications, murdered, lung cancer, renal dysfunction, CVA, inadvertently received Benazapril instead of the study drug, Quinapril, by the internal medicine resident. There have been a total of 21 adverse events reported from Denver General Hospital, University Hospital,

Continuation of Detail Summary Sheet for 92/123

Denver Veterans' AMC, and FAMC. Five of these events were from FAMC; 3 were cardiovascular related (2 unstable angina, 1 MI) and two were non-cardiovascular related (1 viral infection and 1 questionable lung mass). Amendment 6 "Substudy of the QUIET: Ace Gene Polymorphism in Coronary Artery Disease" was approved by the IRC on 7 Dec 93. The first followup patient will have blood drawn for the substudy on 8 Mar 94.

Publications and Presentations: None.

Detail Summary Sheet

-
- (1) Date: 7 Mar 95 (2) Protocol #: 92/125 (3) Status: Terminated
-
- (4) Title: The Relationship Between High Resolution Electro-cardiography and Ventricular Ectopy in Hypertensive Patients with Left Ventricular Hypertrophy: A Pilot Study
-
- (5) Start Date: 1992 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Richard Shea, CPT, MC (8) Facility: FAMC
-
- (9) Dept of MED/Cardiology (10) Associate Investigators
-
- (11) Key Words: Mark Dorogy, MD
Aryo Oopick, MD
William Highfill, MD
David Boike, MD
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: MAR b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To establish the relationship between echocardiographically determined LV mass, ectopy by Holter monitor, and abnormalities of the SAEIIG on hypertensive patients with LVH.
- (16) Technical Approach: Prospective study of hypertensive patients. We obtain echo, Holter, and SAEIIG data and analyze in context of LV Mass vs percent of ectopy vs abnormal SAEIIG criteria.
- (17) Progress: Enrollment continues at slower than predicted rate. Initial data suggests no relationship between LV mass and SAEIIG data, but more patients are needed. Negative results are still significant. Study design appears good. Results comparable to data available in literature.
FY94: Interim enrollment is complete with a total of 50 patients. Data analysis underway to determine if the study should continue.
- Publications and Presentations: Interim results presented 05 Nov 92 at Army ACP meeting, Cardiology Section, by M. Dorogy.

Detail Summary Sheet

- (1) Date: 30 Sep 95 (2) Protocol #: 92/127 (3) Status: Terminated
- (4) Title: A Phase III, Randomized Comparative Trial of ZDV versus ZDV plus ddI versus ZDV plus ddC in HIV-Infected Patients (NUCOMBO)
- (5) Start Date: 1992 (6) Est Compl Date:
- (7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC
- (9) Dept of MED/Inf. Dis. (10) Associate Investigators
- (11) Key Words: HIV, ZDV, ddI, ddC
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: Apr/Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: To see if combining ddI or ddC with ZDV is more effective than ZDV alone in controlling HIV.
- (16) Technical Approach: See protocol.
- (17) Progress: Too early to compile any data on this study. No progress during this 6-month report period. FY95: Terminated by CPCRA.
- Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 92/130 (3) Status: Completed

(4) Title: Antigen-Specific Immunoglobulin and Lymphocyte Responses in Systemic Lupus Erythematosus Patients Following Immunization with Three Clinically Relevant Vaccines

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: Nicholas Battafarano, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Allergy (10) Associate Investigators
Michael Lieberman, LTC, MC
Raymond Enzenauer, MAJ, MC
Daniel F. Battafarano, MAJ, MC
Lawrence Larson, MAJ, MC
David Goodman, COL, MC

(11) Key Words:
lupus
systemic lupus erythematosus
immunizations

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 53
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine immunization responses in systemic lupus, erythematosus patients to develop practical immunization prescriptions for these patients.

(16) Technical Approach: Pre-immunization: Clinical evaluation immunoglobulin levels, lymphocyte responses; Immunize with pneumococcal, H. Influenza and test toxoid immunizations; Post-immunization: Clinical evaluation immunoglobulin levels, lymphocytes responses.

(17) Progress: Excellent - Patients have agreed to participate, 6 enrolled in test validation group, local injection inflammation has occurred as expected in a few patients. No difference in either group and all easily treated with tylenol, aspirin or NSAIDS. Symptoms score, red area at site of injection. FY93: The protocol was approved at BAMC with former FAMC AI, Daniel Battafarano, MAJ, MC, at BAMC with Steven Older, MAJ, MC, and Dennis Dyer, MAJ, MC, for a joint effort. During this reporting period 20 subjects were enrolled at FAMC for a total of 51, and 23 subjects enrolled at BAMC. FAMC 35/51 SLE completed; BAMC 0/23 are completed but will complete by May-July, 1993. FY94: Since the last update a total of 79 patients were enrolled; 53 at FAMC and 25 at BAMC. 73 of those 79 completed the 3-month followup period; 48 at FAMC and 25 at BAMC. The results of the antigen-specific

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antibody levels have been presented at two national meetings. However, the correlation of the responses with the other clinical and immunological variables still requires analysis. Some of the subjects will need followup evaluation on the basis of this analysis.

FY95: All clinical laboratory work is completed. Data is being analyzed and manuscript is being written to submit for publication.

Publications:

ACR Abstract, "Antigen-Specific Antibody Responses in Lupus Patients Following Immunization." Arthritis Rheum 1993;36(9):S187.

Presentations:

American College of Rheumatology, 1993 Annual Meeting, Nov 93.

Harold Nelson Symposium, The 1994 Annual Meeting of the Association of Military Allergists, Feb 94.

Detail Summary Sheet

(1) Date: 11 Jul 95 (2) Protocol #: 92/138 (3) Status: Completed

(4) Title: A Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium Avium Complex (MAC) Disease in HIV-Infected People

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Inf.Dis. (10) Associate Investigators

(11) Key Words:
HIV
MAC
azithromycin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 15 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and efficacy of oral azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 cell count of <100/mm.

(16) Technical Approach: See protocol.

(17) Progress: Of 15 patients screened 11 were randomized to Rx/placebo; three chose not to continue; one was MAC+ - failed screen; one waiting for screen cultures to qualify.
FY95: Pfizer doing final analysis.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: Sep 95 (2) Protocol #: 92/142 (3) Status: Completed

(4) Title: Clarithromycin in Combination with Omeprazole or Omeprazole as a Single Agent for the Treatment of Patients with Duodenal Ulcers

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words: duodenal ulcer MAJ Steven Hammond
MAJ Scot Lewey
LTC Milton Smith

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if omeprazole plus clarithromycin is more effective in preventing ulcer recurrence than omeprazole plus placebo.

(16) Technical Approach: Double blind randomized multi-center trial with endoscopic followup for recurrence.

(17) Progress: No patients enrolled to date; still awaiting FDA approval; anticipate start 1 Sep 93.

FY94: Two patients continue in final followup phase. No further enrollment.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 92/144 (3) Status: Ongoing

(4) Title: Double-Dummy, Double-Blind, Randomized, Single-Center Study on the Effect of Hormone Replacement Therapy on Blood Pressure

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: William Georgitis, COL, MC (8) Facility: FAMC

(9) Dept of MED/Endocrine (10) Associate Investigators
Shirley Spencer, Ped Pharm

(11) Key Words:
hormone replacement Rhonda Wagner, CPT, AN
blood pressure

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 36
d. Total Number of Subjects Enrolled to Date: 51
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine estrogen replacement therapy effects on blood pressure in post menopausal women.

(16) Technical Approach: This is a 6-month study of 100 women assigned to either Premarin 0.625mg/day, placebo shoulder patch; or Estraderm 0.05mg patch, placebo pill/day. Blood, urine and blood pressure will be monitored.

(17) Progress: To date 18 patients enrolled. One patient dropped out secondary to rash induced by patch adhesive and spotting.

FY94: Subject enrollment continues at a slower rate than expected, 50 to date, may require one year more to enroll a total of 100 subjects.

FY95: Forty-seven subjects have completed protocol. Four on medications and will complete study with tentative plan to close enrollment at this time.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 93/103 (3) Status: Terminated

(4) Title: A Randomized, Comparative, Prospective Study of Daily Trimethoprim/Sulfamethoxazole (TMS) and Thrice Weekly TMS for Prophylaxis Against PCP in HIV-Infected Patients

(5) Start Date: Oct 92

(6) Est Compl Date: 1994

(7) Principal Investigator:
Wheaton Williams, MAJ, MC

(8) Facility: FAMC

(9) Dept of Med/Infect Dis

(10) Associate Investigators

(11) Key Words:

HIV, prophylaxis, PCP, trimethoprim, sulfamethoxazole

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sept b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: None

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate the safety and efficacy of two dose regimens (daily or 3x a week) of Trimethoprim/Sulfamethoxazol (TMP/SMX) in the prevention of Pneumocystis carinii pneumonia (PCP) in high-risk HIV-infected patients.

(16) Technical Approach: There will be two drug regimens, TMP/SMX daily or 3x a week (Monday, Wednesday and Friday). Patients will be assigned therapy according to a prepared randomization schedule.

(17) Progress: No patients enrolled. Change in PI during FY. FY95: Terminated.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 4 Oct 94 (2) Protocol #: 93/104 (3) Status:Terminated

(4) Title: A Randomized, Prospective, Double-Blind Study Comparing Fluconazole with Placebo for Primary and Secondary Prophylaxis of Mucosal Candidiasis in HIV-Infected Women (CPCRA 010)

(5) Start Date: Oct 92 (6) Est Compl Date: 1995

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators

(11) Key Words:
HIV, prophylaxis, Candidiasis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: None
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate the efficacy of Fluconazole vs. placebo for the prevention of Candida esophagitis and vaginal/oropharyngeal candidiasis in HIV-infected women.

(16) Technical Approach: Patients will be assigned one of the two drug regimens, Fluconazole or placebo weekly, according to a prepared randomization schedule.

(17) Progress: None. Change of PI during FY.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Nov 94 (2) Protocol #: 93/105 (3) Status: Completed

(4) Title: Amlodipine Study of the Angina Population

(5) Start Date: 1993

(6) Est Compl Date: 1994

(7) Principal Investigator:
Tally Culclasure, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators
Brian Horvath, MAJ, MC
Mike McBiles, LTC, MC

(11) Key Words:
Amlodipine, angina, IND

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine safety and efficacy of amlodipine as replacement therapy for other antianginal medications in patients with chronic angina.

(16) Technical Approach: Randomized, double-blind, placebo controlled, multi-center trial. Ten subjects per site. Phase I baseline 4 weeks; Phase II is 4 weeks of taper-off heart medication period, then assignment to study drug treatment for 4 weeks; Phase III is an optional 3 month treatment on open label.

(17) Progress: None. CIRO approved 2 Sep 93. FY95: The duration of active enrollment in the study was from 8 Feb 94 to 1 Sep 94. Five patients were enrolled and completed the study. No serious adverse events occurred. One patient #0796 ECS developed increased tight bilateral leg edema. This may be secondary to amlodipine; however, two weeks after drug was discontinued, edema persisted. The study is now closed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: Dec 95 (2) Protocol #: 93/111 (3) Status: Terminated

(4) Title: An Open Protocol for the Use of Agrelin (Anagrelide) for Patients with Thrombocythemia

(5) Start Date: 1993

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Daniel Tell, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators
Michael Johnson, MAJ, MC
Scott Kruger, MAJ, MC
Richard Tenglin, LTC, MC

(11) Key Words:
IND, anagrelide,
thrombocytopenia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if anagrelide is a safe and effective treatment to reduce the number of platelets in the blood. This is also a dose ranging study.

(16) Technical Approach: Open label study, 3-month supply of drug in 0.5 mg and 1.0 mg capsules.

(17) Progress: One patient was enrolled but was taken off study due to non-compliance. FY95: No progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: Dec 95 (2) Protocol #: 93/112 (3) Status: Terminated

(4) Title: A Phase I-II Study of Daily Carboplatin and Simultaneous Accelerated Hyperfractionated Chest Irradiation Followed by Single Agent Carboplatin in Patients with Regionally Inoperable (Stages IIIa and IIIb) Non-Small Cell Lung Cancer

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:
carboplatin, radiation therapy
lung cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To improve response rates by combining radiation therapy (standard treatment) with carboplatin chemotherapy and to study the side effects of this treatment

(16) Technical Approach: Initial treatment is daily chest irradiation and intravenous carboplatin chemotherapy (except on weekends) for four weeks. Rest period of 3-4 weeks between three cycles of treatment.

(17) Progress: No progress. FY95: No progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: Dec 95 (2) Protocol #: 93/113 (3) Status: Terminated

(4) Title: A Pilot Phase II Study of Induction Therapy with Daily Etoposide, Daily Cisplatin and Simultaneous Chest Irradiation Followed by Four Cycles of Consolidation Cisplatin/Etoposide Therapy in Limited Stage Small Cell Lung Cancer

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daneil Tell, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:
lung cancer, etoposide,
cisplatin, radiation therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate a new combination of this standard treatment.

(16) Technical Approach: Per University of Colorado Cancer Center Clinical Trial Protocol.

(17) Progress: No progress. FY95: No progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 Jan 95 (2) Protocol #: 93/114 (3) Status: Terminated

(4) Title: Parathyroid Hormone-Related Peptide in Connective Tissue Disease

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Arnold Asp, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Endo (10) Associate Investigators
LTC Arnold Asp

(11) Key Words: connective tissue disease MAJ James Singleton
CPT Matthew Schofield

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if PTH&P levels are elevated in connective tissue disease.

(16) Technical Approach: Open, repeated measures comparison of controls, rheumatoid arthritis and scleroderm patients.

(17) Progress: Thirteen subjects of projected 63 total obtained. Terminated due to closure of GME.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Feb 95 (2) Protocol #: 93/121 (3) Status: Terminated

(4) Title: Outpatient Screening for Sleep Apnea

(5) Start Date: 1993

(6) Est Compl Date: 1994

(7) Principal Investigator:
Hai Bui, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/

(10) Associate Investigators
William Reed, MAJ, MC

(11) Key Words:
sleep apnea,
screening method

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Feb b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Develop an inexpensive, convenient method of
screening for sleep apnea.

(16) Technical Approach: Record patients.

(17) Progress: Awaiting software sound recording translator.

FY94: Have acquired software for digital sound recording and are
proceeding to enroll patients. FY95: Terminated due to loss of
personnel to perform study.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 93/128 (3) Status: Terminated

(4) Title: The Efficacy of a Standardized Acupuncture Regimen and Amitriptyline compared with Placebo as a Treatment for Pain Caused by Peripheral Neuropathy in HIV-Infected Patients (CPCRA 022)

(5) Start Date: Apr 93

(6) Est Compl Date: 1995

(7) Principal Investigator:
Wheaton Williams, MAJ, MC

(8) Facility: FAMC

(9) Dept of Med/Infect Dis

(10) Associate Investigators
Jeffrey Casserly, PA-C

(11) Key Words:

HIV, acupuncture, amitriptyline, neuropathy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr/Oct b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the separate and combined efficacy of a standardized acupuncture regimen and amitriptyline on the relief of pain due to HIV-related peripheral neuropathy and on the quality of life of HIV-infected patients.

(16) Technical Approach: Randomized, modified double-blind, 2x2 factorial, multicenter clinical trial. Patients will be treated for 14 weeks. There will be a 4-week post treatment followup to assess short term relief of pain. Patients will be randomized according to schedules prepared to ensure an approximate allocation ration of 1:1:1:1. Use of amitriptyline or placebo will be double-blind. Although the acupuncturist cannot be blinded to acupuncture or alternate point treatment, the patient will be blinded (modified double-blind design).

(17) Progress: The protocol was amended 1 Jun 93. One subject enrolled since FY93 APR. Change of PI in FY94. FY95: Terminated.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Apr 95 (2) Protocol #: 93/129 (3) Status: Completed

(4) Title: A Randomized, Comparative, Placebo-Controlled Trial of the Safety and Efficacy of Oral Ganciclovir for Prophylaxis of Cytomegalovirus (CMV) Retinal and Gastrointestinal Mucosal Disease in HIV-Infected Individuals with Severe Immunosuppression. CPCRA 023.

(5) Start Date: 1993

(6) Est Compl Date: 1995

(7) Principal Investigator:
Wheaton Williams, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Inf. Dis.

(10) Associate Investigators

(11) Key Words:

cytomegalovirus (CMV)
ganciclovir

Robert H. Gates, LTC, MC
Jeffrey Casserly, PA-C

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr/Oct b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and efficacy of oral ganciclovir for prophylaxis against CMV retinal and gastrointestinal mucosal disease in HIV-infected patients with severe immunosuppression.

(16) Technical Approach: See protocol.

(17) Progress: One subject was enrolled since the last 6-month review. FY95: Enrollment closed. FAMC's patient withdrew himself from study drug. Died within 6 months of AIDS, not related to study drug.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Apr 95 (2) Protocol #: 93/130 (3) Status: Ongoing

(4) Title: Calcitonin Response to Pentagastrin Stimulation Testing After Near-Total Thyroidectomy and Radioactive Iodine Ablation

(5) Start Date: 1993 (6) Est Compl Date: Jun 96

(7) Principal Investigator: Arnold A. Asp, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Endocrine (10) Associate Investigators

(11) Key Words: radioactive iodine
medullary carcinoma
thyroid
Michael Rensch, CPT, MC
Michael McDermott, LTC, MC
William Georgitis, COL, MC
Reed Christensen, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___ Apr ___ b. Review Results: ___
c. Number of Subjects Enrolled During Reporting Period: ___
d. Total Number of Subjects Enrolled to Date: ___ 3 ___
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: to establish a range of stimulated calcitonin values following near-total thyroidectomy and determine the effect of radioactive iodine upon these values.

(16) Technical Approach: Open, repeated measures prospective study.

(17) Progress: Two patients enrolled; calcitonin batched and performed annually. Investigators were changed since the FY93 Annual Progress Report, and one new subject enrolled. FY95: No progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Apr 95 (2) Protocol #: 93/131 (3) Status: Completed

(4) Title: A Retrospective Evaluation of the Use of the Bard Liver Biopsy Needle: Adequacy of Specimens and Complications

(5) Start Date: 1993 (6) Est Compl Date: 30 Jun 94

(7) Principal Investigator: Spencer Root, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words: bard liver biopsy needle Kenneth E. Sherman, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We will attempt to quantitatively evaluate biopsy parameters and objectively determine comparative efficacy of the Bard Monopty needle to standard liver biopsy methods.

(16) Technical Approach: To analyze the biopsy size, quality and types of complications associated with these 18g needles. There are no safety concerns associated with this study as it will be retrospective and involve only records review.

(17) Progress: Review charts, the study is ongoing. There has been some delay in completion of the chart review due in part to some difficulty in obtaining documents necessary to complete the review.

FY95: Study completed. Manuscript in progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 93/135A (3) Status: Completed

(4) Title: Gastroenterologic Service Training Using Laparoscopic Techniques in the Swine (Sus Scrofa)

(5) Start Date: 1993

(6) Est Compl Date:

(7) Principal Investigator:
Peter R. McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IACUC Review: Apr b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Facilitate training of residents/fellows, nurses in laparoscopy.

(16) Technical Approach: Animal model to simulate human surgery.

(17) Progress: Bi-annual labs have been conducted; study very successful, wish to continue bi-annual.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 93/136 (3) Status: Completed

(4) Title: A Double-Blind, Randomized, Multi-Dose, Placebo-Controlled, Parallel Group Dose Ranging Study to Evaluate the Effects of MK-0591 in Induction of Symptomatic and Endoscopic Remission in Patients with Active Mild to Moderate Ulcerative Colitis. IND#41-060 (MK-0591; Protocol #024-00) AND Amendment #1 (MK-591; Prot No 024-01 And addendum "Open Label-Extension Study to Evaluate the Safety and Tolerability of MK-0591 for 12 months in Patients with Mild to Moderate Ulcerative Colitis".

(5) Start Date: 1993

(6) Est Compl Date: 1995

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:

IND

ulcerative colitis

MAJ Robert Sudduth

MAJ Dirk Davis

MAJ Scot Lewey

MAJ Spencer Root

MAJ Steve Hammond

MAJ Thomas Kepczyk

LTC Milton Smith

Laura Farber, RN

Sofia DeAngelis, RN

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The study is to determine if MK-0591, an investigational drug, is safe and effective in the treatment of ulcerative colitis.

(16) Technical Approach: Per protocol.

(17) Progress: New study. FY94: Enrolled five total; 3 now in open label continuation. Multiple amendments, addendums, advertising materials, changes of investigators occurred since the study was originally approved. AE reported, see IRC minutes Mar 94. Amendment 2 and addendum IRC approved 20 Jul 93; Amendment 3 IRC approved 5 Oct 93. FY95: MSD evaluating data. No AE's related to FAMC subjects enrolled in this study. Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 93/137 (3) Status: Ongoing

(4) Title: Aspirin in the Prevention of Neoplastic Polyps--A MultiCenter Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators
Sophia DeAngelis, RN
Spencer Root, MAJ, MC
Robert Sudduth, MAJ, MC
Dirk Davis, MAJ, MC
Stephen Lawrence, MAJ, MC

(11) Key Words: neoplastic polyps

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To investigate the efficacy of aspirin in preventing the recurrence of neoplastic polyps of the large bowel.

(16) Technical Approach: Conduct a randomized, double-blind, placebo-controlled clinical trial. Test the hypothesis that aspirin taken orally will reduce the occurrence of neoplastic polyps among those patients with a recent history of these tumors.

(17) Progress: New study. FY94: No patients enrolled to date. Still awaiting funding from NCI. Anticipate enrollment to start in Jun-Jul 94. FY95: Eight patients enrolled to date.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 11 Jul 95 (2) Protocol #: 93/138 (3) Status: Terminated

(4) Title: A Screening Study for Myocardial Sarcoidosis Comparing Transesophageal Echocardiography, Transthoracic Echocardiography, Electrocardiography, Gallium-67 Scintigraphy and 99mTcSestamibi Scintigraphy

(5) Start Date: 1993

(6) Est Compl Date: 1994

(7) Principal Investigator:
David Schachter, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators

(11) Key Words:
sarcoid
electrocardiography
gallium, sestamibi

Mike McBiles, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Assess most effective non-invasive test for detecting sarcoidosis in the heart.

(16) Technical Approach: Compare electrocardiography, transthoracic and transeophageal echocardiography, gallium-67 and 99mTc sestamibi scintigraphy.

(17) Progress: No notable difference among electrocardiography and echocardiography. Still await results of both scintigraphy. FY95: Negative study.

Publications: Abstract, Jul 94, Chest;

Presentation: Am College of Chest Physicians, New Orleans, FY94.

Detail Summary Sheet

(1) Date: 6 Jun 95 (2) Protocol #: 93/141 (3) Status: Terminated

(4) Title: A Controlled Trail of Implantable Cardiac Defibrillators Versus Medical Anti-Arrhythmic Drug Therapy

(5) Start Date: 1993

(6) Est Compl Date:

(7) Principal Investigator:
Richard Davis, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators
Koonlawee Nademanee, MD,
(PI, DGH)

(11) Key Words:
cardiac defibrillator

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether ICD placement reduces total mortality when compared to conventional antiarrhythmic drug therapy. Secondary objectives include an economic assessment of the relative cost-effectiveness of the alternative treatment options and a quality-of-life evaluation.

(16) Technical Approach: 200 patients will be recruited for the pilot and a total of at least 1,000 patients recruited for the full-scale trial. The patients will be recruited at FAMC and referred to Dr. Nademanee for enrollment in the study.

(17) Progress: FY94: Four patients were enrolled to date, one from FAMC. One adverse event was reported for exacerbation of congestive heart failure. The subject was implanted with ICD and managed on amiodarone by his private cardiologist. This event was not thought to be study drug related. The pilot portion of the study complete, and safety and efficacy data will be reviewed in June 1994 to see if data warrants a full scale trial. FY95: FAMC was eliminated as an enrollment site due to lack of activity. Sponsor will probably complete or terminate study in near future.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 11 Jul 95 (2) Protocol #: 93/142 (3) Status: Ongoing

(4) Title: Hypertension Optimal Treatment International Study

(5) Start Date: 1993

(6) Est Compl Date: 1996

(7) Principal Investigator:
Jane Yeun, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Nephrology

(10) Associate Investigators

(11) Key Words:
hypertension
diastolic blood pressure
optimal blood pressure

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 25

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". see progress.

(15) Study Objective: Determine optimal diastolic blood pressure goal and if ASA is efficacious in hypertensive patients.

(16) Technical Approach: Patients randomized to 3 BP goals, 90, 85, 80 mm Hg diastolic. Patients also randomized to ASA vs placebo. Endpoints cardiovascular events and death.

(17) Progress: Protocol recently approved, in process of enrolling patients.

FY94: Closed to subject enrollment 30 Apr 94, 25 enrolled. Blood pressure will be monitored at 1-3 month intervals.

FY95: Closed to subject enrollment. One patient dropped out because she no longer desired to participate. Blood pressures are currently being monitored at 3-6 month intervals in the remaining 24 patients. No endpoint reached in any patient. One patient in study on verapamil and HCTZ developed bruising from an acquired Factor VIII inhibitor, responded to steroids. Problem is thought unrelated to the Verapamil/HCTZ/or ASA vs. placebo. Code was broken for patient. He was on placebo. Merck provided several worldwide adverse events.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Aug 95 (2) Protocol #: 93/143 (3) Status: Ongoing

(4) Title: Does Gastroesophageal Reflux Induce Myocardial Ischemia?

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: George Winters, CPT, MC (8) Facility: FAMC

(9) Dept of MED/GI (10) Associate Investigators

(11) Key Words: gastroesophageal reflux myocardial ischemia Peter McNally, LTC, MC Mike McBiles, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Feb/Aug b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if esophageal acid infusion induces myocardial ischemia; (2) to determine the nature of cardiovascular responses (if any) to gastroesophageal reflux simulated by esophageal acid infusion; (3) to correlate patient symptoms with objective findings.

(16) Technical Approach: Patients will be assigned per study algorithm to recreate the conditions found in gastroesophageal reflux in order to see what affects it may have on the heart.

(17) Progress: Approved in Aug 93 by the IRC as a 10-subject pilot. No progress to date. FY94: Having trouble recruiting subjects, two enrolled to date. Equipment breakdown should be fixed soon. Protocol exclusion criteria amended 5 Jul 94. FY95 Feb: A \$5,000 catheter needed to perform test was broken---now fixed. The Pharmacy terminated the position for making O.INCHL---now fixed. Dr. Winters has been on InPatient Rotations---now fixed. Hope to rapidly recruit patients over the next 6-12 months. FY95 Aug: New manometry equipment is to be delivered this month in support of this study. Resolved issue of Pharmacy not storing O.INCHL for Bernstein test. Two patients enrolled. Hope to enroll 20 patients by November.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Nov 94 (2) Protocol #: 93/148 (3) Status: Ongoing
(4) Title: Patient Utilities for Screening with Flexible Sigmoidoscopy
(5) Start Date: 1993 (6) Est Compl Date: 1994
(7) Principal Investigator: William Reed, MAJ, MC (8) Facility: FAMC
(9) Dept of MED/Int. Med. (10) Associate Investigators
Michael J. Weaver, COL, MC
(11) Key Words:
utility assessment, sigmoidoscopy
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___ Nov ___ b. Review Results: ___
c. Number of Subjects Enrolled During Reporting Period: ___
d. Total Number of Subjects Enrolled to Date: ___
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To determine utility assessments for screening
flexible sigmoidoscopy for several patient and physician groups. Our
secondary objectives are to determine whether demographic factors
influence utility assessment, to assess how published decision analyses
on screening sigmoidoscopy will be affected, and to assess test-retest
reliability of our methods over a three month period.

(16) Technical Approach: In addition to obtaining demographic
information from subjects, we will use the techniques of the standard
reference gamble and time tradeoff. Will assess the risk they are
willing to take to avoid a lifelong protocol of regular screening
flexible sigmoidoscopy. We hope to repeat the utility assessments
approximately three months after the initial interview.

(17) Progress: New study. FY95: Approximately 20 subjects enrolled
without complications.

Publications: None.

Presentations: Preliminary data presented at the Army ACP meeting in
FY94.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-100

A Prospective Controlled Trial of the Efficacy of Maloney Versus Through-the-Scope Hydrostatic Balloon Dilators in the Treatment of Benign Esophageal Strictures

START DATE: Oct 93 EST COMP DATE: Oct 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: balloon dilator, Maloney, esophageal strictures

OBJECTIVE: To determine whether one type of dilator is better than another type for the treatment of benign esophageal strictures.

TECHNICAL APPROACH: Randomize up to 100 subjects to the dilators; perform interim analysis after 50 subjects.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: No progress. Original PI PCS'd. Will investigate addition of new collaborators or possibly change to multicenter (MAMC;TAMC). Terminated due to fellowship closure.

PUBLICATIONS: None

PRESENTATIONS: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-103

The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Coronary Heart Disease and Left Ventricular Dysfunction "SWORD" Survival with Oral D-Sotalol. (IND #23,933)

START DATE: Dec 93 EST COMP DATE: Dec 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Mitchel Kruger, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Tally Culclasure, CPT, MC, Ann Richardson, RN

PERIODIC REVIEW DATE: 1 Nov 94 REVIEW RESULTS: Continue

FUNDING: FACT

GIFTS: Bristol-Myers, IND drug & placebo

KEY WORDS: D-sotalol

OBJECTIVE: To determine if oral d-sotalol reduces the risk of death in patients who had a myocardial infarction and have left ventricular dysfunction.

TECHNICAL APPROACH: Approximately 20-30 adult patients will be randomized to placebo or d-sotalol 100 mg BID for the first 7 days. If tolerated, the dose will be increase to d-sotalol 200 mg or placebo BID for the remainder of the study.

PROGRESS:

Number of subjects enrolled to date: 2

Number of subjects enrolled for reporting period: 2

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): One patient died.

Summary of prior and current progress: Entrance criteria are very strict. Many patients are not eligible due to creatinine clearance restrictions. FY95: Two patients enrolled. One subject died and the other appears to have experienced no serious side effects. On 3 Nov 94, C, DCI, was notified of immediate termination by the sponsor of this study. Documentation was provided to the IRC. Question was raised whether the two FAMC subjects enrolled in this study were on drug or placebo. One subject died and the other appears to have experienced no serious side effects. The sponsor has not released this information. Bristol-Myers Squibb reported "Of the 2762 randomized patients on whom data was available for the DSMC review, there were 82 (3.0%) deaths overall. Fifty-four (3.9%) deaths occurred in the 1373 patients randomized to d-sotalol and 28 (2.0%) in the 1389 patients randomized to placebo."

PUBLICATIONS: None. PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-104

Detection of Measles Virus in Tissue Samples from Patients with Crohn's Disease by Polymerase Chain Reaction (PCR) Testing

START DATE: Nov 93 EST COMP DATE: Nov 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scot Lewey, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Kenneth Sherman, MAJ, MC, John Singleton, MD

PERIODIC REVIEW DATE: 1 Nov 94 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: measles virus, Crohn's Disease, polymerase chain reaction testing

OBJECTIVE: To confirm the presence or absence of Measles virus RNA in tissue samples from subjects with Crohn's Disease as compared to controls without inflammatory bowel disease.

TECHNICAL APPROACH: Pilot study of 10 adult patients undergoing diagnostic colonoscopy with biopsy for other indications will be tested using PCR assay.

PROGRESS:

Number of subjects enrolled to date: 30

Number of subjects enrolled for reporting period: 30

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Ten Crohn's subjects; 10 control subjects; 10 ulcerative colitis subjects. The measles virus has been developed and validated with control samples of wild measles virus. Control samples of colonic tissue from normal volunteer subjects were tested with and without measles virus added. Initial five subjects each with Crohn's disease, ulcerative colitis and normal colon tissue were tested for presence of measles virus RNA by PCR. None had detectable measles virus RNA. Additional samples are to be tested.

FY95: This protocol was modified with IRC approval to include testing of archival and prospectively identified surgical resected specimens from subjects with Crohn's disease. In addition, subjects are continuing to be solicited for pinch mucosal biopsy samples when colonoscopy is required for their evaluation. To date approximately 15 subjects with Crohn's disease, 15 subjects with ulcerative colitis, and 20 normal controls have been tested for presence of measles virus by PCR.

Continuation of FY95 Detail Summary Sheet 94-104

No measles virus was detected but spiked controls have been positive. An assay for beta-actin RNA is being run to confirm the ability to detect RNA in colonic tissue samples. As requested from the IRC, a PCR assay for Mycobacterium paratuberculosis is being run on these samples as well.

PUBLICATIONS: abstract, Gastroenterology, Apr 95, vol 108.

PRESENTATIONS: 11th annual Scientific Program of the Army ACP, William Beaumont Gastroenterology Symposium, Oct 26, 1994.

Air Force Regional American College of Physicians Meeting, Colorado Springs, CO, Feb 14 95.

American Gastroenterological Association meeting in San Diego, CA, May 17, 95.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-107

Breast and Colon Cancer Agenetic Association Requires Synchronous and Metachronous Screening for both Cancers

START DATE: Jan 94 EST COMP DATE: Jan 97 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Dennis Ahnen, MD, Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Laura Farber, RN, Sofia DeAngelis, RN, Daniel Tell, LTC, MC, Jerry Sims, COL, MC, Kevin Rak, MAJ, MC

PERIODIC REVIEW DATE: 3 Jan 95 REVIEW RESULTS: Terminate

FUNDING: NA

GIFTS: NA

KEY WORDS: cancer screening, genetic association

OBJECTIVE: To determine if an association between breast cancer and colon cancer exists.

TECHNICAL APPROACH: Prospective colonoscopic evaluation of all women with a new diagnosis of breast malignancy; prospective screening (mammographic and manual examination) of all women with a new diagnosis of colon cancer; screening (colorectal or breast) for all women identified from our tumor registry with a histologic diagnosis of colon or breast malignancy; evaluation of the chromosome 2, repetitive polymorphism as a marker for synchronous and metachronous breast/colon cancer.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Retrospective review of FAMC records confirms importance of this study. Still awaiting consideration for grant funding. Enrollment on hold for now.

FY95: Study was not approved for funding.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-108

Barrett's Esophagus and Adjuvant Chemotherapy for Breast Cancer.
Is There an Association?

START DATE: Jan 94 EST COMP DATE: Jan 97 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Dennis Ahnen, MD, Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Laura Farber, RN, Sofia DeAngelis, RN, Daniel Tell, LTC, MC, Jerry Sims, COL, MC

PERIODIC REVIEW DATE: 3 Jan 95 REVIEW RESULTS: Terminate

FUNDING: NA

GIFTS: NA

KEY WORDS: Barrett's esophagus, breast cancer

OBJECTIVE: To determine if an association exists between Barrett's esophagus and treatment of breast cancer exists.

TECHNICAL APPROACH: Prospective endoscopic evaluation of women pre- and post adjuvant chemotherapy for breast cancer for the evolution of Barrett's esophagus; prospective evaluation of prevalence of Barrett's esophagus among women with breast cancer (+/- chemotherapy); prospective, randomized, placebo-controlled trial to evaluate the effectiveness of intercurrent administration of omeprazole to prevent development of Barrett's esophagus among women with breast cancer undergoing adjuvant chemotherapy.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Still awaiting decision on funding re: Women's Health Awards. If 2nd run of awards do not fund this study, we will have to abort. Funding essential for personnel.

FY95: Study was not approved for grant funding.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-109

Partnership for Quality Living: A Multicenter Study to Develop a National Database from Patients with Ulcerative Colitis

START DATE: Sep 93 EST COMP DATE: Sep 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, MAJ, MC, Steve Lawrence, MAJ, MC, Laura Farber, RN

PERIODIC REVIEW DATE: 3 Jan 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: Kabi Pharmacia will provide all survey/questionnaires and postage.

KEY WORDS: Crohn's disease, ulcerative colitis

OBJECTIVE: To gather data and collect information needed to develop new and better treatment options and to improve the quality of life for thousands of sufferers nationwide.

TECHNICAL APPROACH: Prognostic questionnaires will be completed by the physicians three times for each participating patient. Subjects will complete quality of life questionnaires three times. Participation Tracking Forms, completed when prescriptions are filled at the pharmacy, will capture information on patient compliance.

PROGRESS:

Number of subjects enrolled to date: 6

Number of subjects enrolled for reporting period: 3

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Four patients entered into national databank. Will need to maintain study to permit continued enrollment. FY95: Continuing to enter patients in the database.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-110

The Pharmacokinetics of Methylprednisolone in Asthmatic Patients with Acute Bronchospasm

START DATE: Jan 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: John Walker, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: P. Dennis Dyer, LTC, MC, Michael O'Connell, MAJ, MC, Matthew Schofield, CPT, MS

PERIODIC REVIEW DATE: 3 Jan 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: bronchospasm, methylprednisolone

OBJECTIVE: To investigate how methylprednisolone is metabolized by asthmatic patients who are acutely ill with significant respiratory compromise.

TECHNICAL APPROACH: Subjects who meet entry criteria will be given one oral dose of the drug. Following ingestion of the drug, serial blood specimens will be obtained which will enable the researchers to determine how quickly the medication is metabolized by the subject's body. At a later date subjects will return for repeat dose and serial blood specimens.

PROGRESS:

Number of subjects enrolled to date: 6

Number of subjects enrolled for reporting period: 6

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Data gathering is progressing. FY95: New PI approved in Aug 95 to replace CPT Ruggerio. Preliminary results appear to suggest a difference in the metabolism of methylprednisolone in patients when they are acutely ill as compared to when they are stable. More patients need to be studied to demonstrate a significant difference.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-113

Randomized Trial of Nortriptyline for Smoking Cessation

START DATE: Aug 94 EST COMP DATE: Aug 97 STATUS: Completed

PRINCIPAL INVESTIGATOR: Michael Weaver, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Int Med

ASSOCIATE INVESTIGATORS: William Reed, LTC, MC, Anita Huttenhower, PharmD., Jaime Soria, MAJ, AN, FAMC; CPT Richard Keller, AN, AMEDD Student Detachment, FSH, TX (U of WA)

PERIODIC REVIEW DATE: 30 Sep 95 REVIEW RESULTS: Completed

FUNDING: DOD/VA

GIFTS: NA

KEY WORDS: nortriptyline, smoking cessation

OBJECTIVE: Treatment of smokers, both with and without a history of past major depression, with a tricyclic antidepressant, nortriptyline, can reduce tobacco withdrawal symptoms and increase long term cessation rates when combined with a behavioral cessation program.

TECHNICAL APPROACH: Placebo-controlled, parallel group trial with randomization stratified by prior history of depression and by study site.

PROGRESS:

Number of subjects enrolled to date: 60

Number of subjects enrolled for reporting period: 60

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress. Grant recently approved. FY95: Study in progress. Approximately 120 enrollees at FAMC completed treatment by the end of the fiscal year. FAMC portion of study is complete. Study continues at the VA.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-114A

Effects of Beta-Blockers on Intracellular Cyclic Guanylate Nucleotide Generation in Guinea Pig (Cavia porcellus) Airway Smooth Muscle

START DATE: Jan 94 EST COMP DATE: May 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Vincent Dubravec, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: Michael O'Connell, MAJ, MC, Paul Schkade, MAJ, MC, Philip Dyer, LTC, MC

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Approved

FUNDING: FACT

GIFTS: FACT

KEY WORDS: beta blockers, smooth muscle

OBJECTIVE: Airway smooth muscle treated with a beta-blocker will show cyclic GMP levels that will correlate with previously studied cyclic AMP levels (protocol 91/138A) if the control of these two nucleotides are coupled via the beta receptor complex; tissue cGMP levels will not correlate with cAMP responses if these two nucleotide generating systems are not coupled via the beta-receptor complex.

TECHNICAL APPROACH: Tracheal strips will be prepared per experimental design and phase 1 and phase 2 performed.

PROGRESS:

Number of subjects enrolled to date: 20

Number of subjects enrolled for reporting period: 20

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Tissue from 20 euthanatized guinea pigs has been processed, and we are currently in the process of running RIAs. We will then evaluate the data to date.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-115A

Propagation of Trypanosoma Brucei in Rodents

START DATE: Jan 94 EST COMP DATE: May 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Infec Dis

ASSOCIATE INVESTIGATORS: Shannon Harrison, COL, MC

PERIODIC REVIEW DATE: Jan 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: sleeping sickness

OBJECTIVE: Definitive diagnosis of African Sleeping Sickness by identification of parasite in blood smears of the patient or in the blood smears of inoculated rodents. More sensitive assessment of disease progression than cytological examination of patient CSF.

TECHNICAL APPROACH: Rats will be inoculated with either the patient's blood or spinal fluid. Rodent blood will be examined periodically for 60 days. Harvested blood will be collected in EDTA tubes mixed with preservative and frozen in liquid nitrogen.

PROGRESS:

Number of subjects enrolled to date: 6

Number of subjects enrolled for reporting period: 6

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Study complete. Rat blood smears collected. If patient develops recurrent symptoms, may need to re-inoculate rodents again in future.

PUBLICATIONS: None.

PRESENTATIONS: Clinical vignette at Colorado American College of Physicians meeting.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-116

Search for the Precursor Cell of Extramammary Paget's Disease in Autopsy Specimens of Axilla, Nipple and Groin Using Immunoperoxidase Markers

START DATE: Feb 94 EST COMP DATE: Feb 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Thomas McGovern, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: James Fitzpatrick, COL, MC, Stephen Groo, MAJ, MC, Sal Fong, MD

PERIODIC REVIEW DATE: 7 Mar 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: Paget's disease, immunoperoxidase markers

OBJECTIVE: Using skin samples from the nipple lines of autopsy specimens, we will stain them with hematoxylin and eosin (H&E) and immunoperoxidase stains which characteristically decorate Paget cells: CEA, EMA and low molecular weight cytokeratins to locate "Tokaer's clear cells" in tissue free of malignancy. Such an immunoperoxidase profile would strongly suggest that these are the progenitor cells of MPD (without underlying ductal carcinoma) and EMPD.

TECHNICAL APPROACH: Biopsy evaluation of 100 autopsy subjects as per objective.

PROGRESS:

Number of subjects enrolled to date: 14

Number of subjects enrolled for reporting period: 10

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Biopsies harvested. No immunostaining done yet. Waiting for more autopsy material.
FY95: We will start viewing stained sections of tissue specimens within the next month.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-117

Comparison of Single-Photon Emission Computed Tomography (SPECT) Analysis of Cerebral Blood Flow with Brain Magnetic Resonance Imaging and Neuropsychological Testing in the Evaluation of Patients with Systemic Lupus Erythematosus with and without Neuropsychiatric Manifestations - A Pilot Study

START DATE: Apr 94 EST COMP DATE: Oct 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Alan Erickson, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/Rheum

ASSOCIATE INVESTIGATORS: Albert Lambert, MAJ, MC, Kevin Rak, MAJ, MC, Sterling West, COL, MC, MC, Elizabeth Kozora, PhD, NJH

PERIODIC REVIEW DATE: 5 Apr 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: lupus, blood flow

OBJECTIVE: To determine if HM-PAO brain SPECT is better modality than MRI in comparison with neuropsychiatric testing in evaluating SLE patients with and without CNS disease.

TECHNICAL APPROACH: SPECT will be administered as non-standard of care element of this protocol. Data analysis after 20 subjects are studied.

PROGRESS:

Number of subjects enrolled to date: 6

Number of subjects enrolled for reporting period: 4

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No significant data yet.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-118

Immunoregulation and Pathogenesis of Symptomatic, Primary HIV-1 Infection

START DATE: Apr 94 EST COMP DATE: Apr 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Infect Dis

ASSOCIATE INVESTIGATORS: Wheaton Williams, MAJ, MC

PERIODIC REVIEW DATE: 4 Apr 95 REVIEW RESULTS: Continue

FUNDING: HMJF

GIFTS: NA

KEY WORDS: HIV, immunoregulation, pathogenesis

OBJECTIVE: To better understand how the HIV virus changes its form (genetic makeup) as it divides in a patient over time.

TECHNICAL APPROACH: Study of blood and body fluids using special laboratory tests and to establish a bank of properly stored peripheral blood mononuclear cells (PBMC), sera, and other body fluids from this group of patients for potential use in future studies.

PROGRESS:

Number of subjects enrolled to date: 1

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: One patient enrolled at FAMC but terminated early secondary to discharge from service.
FY95: No progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-119A

Evaluation of Different Suture Patterns and Angioplasty Balloons on Vein Graft Anastomoses in the Domestic Pig (Sus scrofa)

START DATE: Oct 93 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Talley Culclasure, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Mark Dorogy, MAJ, MC

PERIODIC REVIEW DATE: Mar 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: anastomoses, suture training, angioplasty

OBJECTIVE: To determine the safety and limitations of angioplasty on vein graft anastomoses in early peri-operative period.

TECHNICAL APPROACH: Vein grafts harvested from the animal will be sutured into place on the carotid artery in an end to side fashion (two touchdowns per vein graft). Two suture styles will be used to replicate the techniques currently used in vascular surgery: 1) running suture and 2) interrupted suture. After completion of the surgical procedure, the vein-graft anastomosis lumen size will be determined by intravascular ultrasound catheters. Appropriate sized balloon catheters will be introduced through the vein graft and balloon angioplasty will be performed. These anastomoses will be visually inspected and then harvested for microscopic evaluation.

PROGRESS:

Number of subjects enrolled to date: 7

Number of subjects enrolled for reporting period: 4

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: On schedule. FY95: Data collection completed. No yet published/submitted.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-120

Urgent Revascularization in Unstable Angina

START DATE: NA EST COMP DATE: NA STATUS: Withdrawn

PRINCIPAL INVESTIGATOR: William Highfill, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: NA REVIEW RESULTS: Withdrawn

FUNDING: NA

GIFTS: NA

KEY WORDS: NA

OBJECTIVE: NA

TECHNICAL APPROACH: NA

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Withdrawn prior to IRC review due to unresolved issues.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-121

The Effect of Estrogen and Ultraviolet Light on the Translocation of Ro/SSA within Human Keratinocytes

START DATE: May 94 EST COMP DATE: May 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scott Bennion, COL, MC

FACILITY/DEPT/SVC: FAMC/Clin Invest/Cell Phys

ASSOCIATE INVESTIGATORS: Kathleen David-Bajar, LTC, MC, Ronald Jackson, PhD

PERIODIC REVIEW DATE: 2 May 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: estrogen, ultraviolet light, keratinocytes

OBJECTIVE: To determine whether estrogens or UVL, singly or in combination, have an effect on the translocation of Ro/SSA from the cell cytoplasm to the cell surface of human keratinocytes. To examine this phenomenon at the ultrastructural level utilizing immunogold labelling to determine the exact location of Ro/SSA within the cell cytoplasm and the cell surface.

TECHNICAL APPROACH: No human subjects will be involved in this study. Keratinocytes are derived from neonatal foreskins which are normally discarded from the Newborn Nursery. The human sera utilized in this study is banked from previous protocols or will be taken from blood drawn for routine laboratory studies in clinical workups of patients. Laboratory methods used in this project are currently being used in the Cell Physiology Service, DCI.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress to date. Work on immunoelectron microscopy utilizing immunogold staining is progressing. Once the technique is perfected the study will be started. FY95: The preliminary research in the development of the immunoelectron microscopy technique is essentially successful and complete. We are planning to evaluate the technique utilizing both RO+ patients' sera and antibodies to oligonucleotides of the RO molecule.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-122A

Photosensitive Lupus Erythematosus: A Women's Disease - Use of Transgenic Mice to Distinguish Mechanisms of Discoid and Subacute Cutaneous Lupus

START DATE: Aug 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kathleen David-Bajar, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: Scott Bennion, COL, MC, David Norris, M.D., Richard Duke, PhD, Ronald Jackson, Ph.D., Kevin Corcoran, MAJ, DVM

PERIODIC REVIEW DATE: Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: lupus erythematosus, antibodies

OBJECTIVE: To define autoimmune keratinocyte destruction, the central component of photosensitive lupus, in women, by defining the disease components in an animal model.

TECHNICAL APPROACH: Produce animal models that mimic human skin disease associated with lupus erythematosus.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Transgenic ICAM-1+ male mice and FVB female mice have been received. Attempts are being made to establish a breeding colony. FY95: A small colony of ICAM-1 mice has been developed. Initial injection experiments using splenic lymphocytes yielded no difference between ICAM-1+ and ICAM-1- animals. Topical application of an irritant substance, sodium laurel sulfate, resulted in dermatitis in the ICAM-1+ mice, and only one of the ICAM-1- mice. Histologic exam showed marked differences in inflammation between these two groups. This experiment will be repeated to confirm these findings. If successful, this procedure should yield adequate quantities of activated, skin-targeted lymphocytes for use in future cell injection experiments.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-123

A Pilot Study of a New Esophageal Cytology Device (Brandt Cytology Balloon) to Evaluate Patients with Barrett's Esophagus for Metaplastic Dysplasia and Malignancy

START DATE: Dec 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scot Lewey, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: Barrett's esophagus, dysplasia, malignancy

OBJECTIVE: Evaluate the safety and utility of the Brandt Esophageal Balloon Cytology device to screen patients with Barrett's esophagus when compared to the current "gold standard" -- endoscopy with surveillance biopsies.

TECHNICAL APPROACH: Per objective.

PROGRESS:

Number of subjects enrolled to date: 20

Number of subjects enrolled for reporting period: 20

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Interim analysis underway.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-124

Evaluation of the Clinical and Cost Effectiveness of Therapy with Clarithromycin Plus Omeprazole Compared to Omeprazole or Ranitidine for the Treatment of Patients with Duodenal Ulcer and Helicobacter Pylori Infection. (IND 31,703)

START DATE: Jul 94 EST COMP DATE: Jan 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, MAJ,, MC, Brian Long, LPN

PERIODIC REVIEW DATE: Jun 94 REVIEW RESULTS: Approved

FUNDING: FACT

GIFTS: Abbott

KEY WORDS: ulcer, Helicobacter pylori, clarithromycin, omeprazole, ranitidine

OBJECTIVE: To determined if clarithromycin, an antibiotic, when given with omeprazole, an anti-ulcer medication, will have a beneficial and cost effective outcome for ulcer disease.

TECHNICAL APPROACH: Ten patients randomized, double-blind, to receive either clarithromycin and omeprazole; omeprazole or ranitidine alone, for 28 days.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Will begin enrollment end of Sept. Study delay due to regulatory review.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-125

A Double-Blinded, Randomized Trial Comparing Zidovudine (ZDV) vs. ZDV + Didanosine (ddI) vs. ZDV + ddI + Nevirapine (NVP) in Asymptomatic Patients on ZDV Monotherapy Who Develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA. (ACTG Protocol #224, Version 2.0) IND#42,003

START DATE: Jul 94 EST COMP DATE: Jul 99 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Inf Dis

ASSOCIATE INVESTIGATORS: Donald Skillman, LTC, MC

PERIODIC REVIEW DATE: 11 Jul 95 REVIEW RESULTS: Terminated

FUNDING: MMCARR

GIFTS: ACTG

KEY WORDS: HIV, RNA, ZDV, ddI, NVP

OBJECTIVE: Prove that a specific change (mutation) in virus appears in the blood before the amount of virus in the blood increases and T4 cells decrease; determine whether adding other anti-HIV medications (Didanosine, Nevirapine) changes the amount of HIV in the blood of those patients who develop the mutant virus; provide information concerning the safety and efficacy of the combination of zidovudine, Didanosine (ddI) and Nevirapine (NVP).

TECHNICAL APPROACH: Per title, objective and ACTG protocol.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No progress.

FY95: Terminated 20 Jun 95 due to PCS of PI.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-126

An Open-Label, Randomized Trial of Four Treatment Regimens for Patients with Disseminated Mycobacterium avium Complex Disease and Acquired Immunodeficiency Syndrome (AIDS). (CPCRA 027, IND#43,458)

START DATE: Jul 94 EST COMP DATE: Jul 98 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Inf Dis

ASSOCIATE INVESTIGATORS: Donald Skillman, LTC, MC

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Terminated

FUNDING: CPCRA

GIFTS: IND drugs

KEY WORDS: AIDS, Mycobacterium avium, clarithromycin, rifabutin, ethambutol, clofazimine

OBJECTIVE: To determine whether there is a difference in treating disseminated Mycobacterium avium infection in AIDS subjects with clarithromycin 500 mg twice a day or clarithromycin 1,000 mg twice a day and if there is a difference in treating with rifabutin or clofazimine.

TECHNICAL APPROACH: As per title, objective, and NIH/CPCRA protocol. Ten subjects to be enrolled at FAMC over the next 2 years with minimum patient followup of 1.5 years.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No progress.

FY95: CPCRA terminated protocol.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-127

A Multicenter, Double-Blind, Randomized Study to Evaluate the Effects of Omeprazole 20 mg B.I.D. Coadministered with Amoxicillin 1 g. T.I.D. in Helicobacter pylori Eradication in Patients with Inactive Duodenal Ulcer. (MK-764 #036 A/M 5/3/94, IND#41,414)

START DATE: Sep 94 EST COMP DATE: Dec 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, MAJ,, MC, Brian Long, LPN

PERIODIC REVIEW DATE: 11 Jul 95 REVIEW RESULTS: Approved

FUNDING: FACT

GIFTS: Astra/Merck

KEY WORDS: ulcer, omeprazole, amoxicillin, Helicobacter pylori

OBJECTIVE: To determine the safety and efficacy of the drug combination in the treatment of duodenal ulcer disease.

TECHNICAL APPROACH: At FAMC 5-15 subjects will be enrolled as per title.

PROGRESS:

Number of subjects enrolled to date: 10

Number of subjects enrolled for reporting period: 7

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): Multiple adverse events world-wide.

None in FAMC subjects.

Summary of prior and current progress: Study initiation was delayed due to internal MSD re-alignment. Anticipate 10-20 patients for enrollment this year. FY95: Ten patients enrolled to date. Still trying to enroll 50 patients nationwide. Would like to extend enrollment period until Dec 95. 10 Oct 95 sponsor closed study.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-129

The Effects of Region-Specific Resistance Exercises on Bone Mass
in Premenopausal Military Women

START DATE: Oct 94 EST COMP DATE: Oct 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael McDermott, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Endo

ASSOCIATE INVESTIGATORS: Reed Christensen, MAJ, MC, Albert
Lambert, MAJ, MC

PERIODIC REVIEW DATE: 1 Aug 95 REVIEW RESULTS: Approved

FUNDING: DWHRP \$35,809

GIFTS: NA

KEY WORDS: bone mass, exercise, women

OBJECTIVE: Investigate the effects of two types of exercise,
aerobic and resistance, on the calcium content of premenopausal
women's bones.

TECHNICAL APPROACH: Prospective, randomized study of 60 healthy
premenopausal women. Physical activity for at least 30 minutes a
session, 3 days a week for a period of 1 year with 1000 mg
calcium intake.

PROGRESS:

Number of subjects enrolled to date: 78

Number of subjects enrolled for reporting period: 78

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): none

Summary of prior and current progress: Study recently approved,
awaiting funding from Defense Women's Health Research Program.

FY95: Seventy-eight patients have been recruited and randomized
into one of two arms of the study: aerobic or resistance
exercises. The baseline bone densities are done and the exercise
programs are underway. No data analysis yet.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-130

Assessment of Dietary Calcium Intake, Physical Activity and Habits Affecting Skeletal Health Among Premenopausal Military Women

START DATE: Sep 94 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael McDermott, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Endo

ASSOCIATE INVESTIGATORS: Reed Christensen, MAJ, MC, Albert Lambert, MAJ, MC, Donna Dolan, CPT, MSC

PERIODIC REVIEW DATE: 1 Aug 95 REVIEW RESULTS: Approved

FUNDING: DWHRP \$15,541

GIFTS: NA

KEY WORDS: calcium, exercise, bone mass

OBJECTIVE: Investigate the effects of various life-style factors such as calcium intake, exercise, smoking and drinking alcohol and caffeine on female bone density.

TECHNICAL APPROACH: Questionnaires to 1000 active duty premenopausal women regarding daily and weekly intakes of specific high calcium foods and calcium supplements, performance of specific aerobic and resistive exercises, and daily quantity of smoking, consumption of alcohol and caffeine containing beverages. Subset of 100 will have blood drawn for CBC and measurement of serum calcium, phosphorus, chloride, alkaline phosphatase, PTH and TSH and will have their bone density measured in the lumbar spine, femoral neck, mid-radius and distal radius by dual energy x-ray absorptiometry.

PROGRESS:

Number of subjects enrolled to date: 1000

Number of subjects enrolled for reporting period: 1000

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Recently approved study, awaiting funding from Defense Women's Health Research Program.

FY95: One thousand surveys have been mailed and approximately 300 returned. Twelve patients recruited for bone density study. No data for analysis yet.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-131

The Effects of Previous Thyroid Hormone Suppression Therapy on the Peak TSH Level Achieved During Whole Body ¹³¹I Scanning for Thyroid Cancer

START DATE: Sep 94 EST COMP DATE: Sep 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael McDermott, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Endo

ASSOCIATE INVESTIGATORS: Reed Christensen, MAJ, MC

PERIODIC REVIEW DATE: 1 Aug 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: thyroid cancer, radioiodine

OBJECTIVE: To determine if thyroid cancer patients who have been on long-term levothyroxine suppression therapy are more likely to have a scintigraphically inadequate elevation of the serum TSH level after a standard 6 week interval of levothyroxine abstinence.

TECHNICAL APPROACH: Prospective study collecting and analyzing data which is normally ordered for clinical reasons in patients who are undergoing ¹³¹I whole body scanning for thyroid cancer followup.

PROGRESS:

Number of subjects enrolled to date: 5

Number of subjects enrolled for reporting period: 5

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: None. Study recently approved. FY95: Five patients enrolled to date. No data analysis yet.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-132

Effect of Shiitake Mushrooms on Blood Eosinophil Count: A Pilot Study.

START DATE: Sep 94 EST COMP DATE: Mar 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Vincent Dubravec, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: Paul Schkade, MAJ, MC, P.Dennis Dyer, LTC, MC

PERIODIC REVIEW DATE: Oct 94 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: eosinophilia, mushroom ingestion

OBJECTIVE: To confirm increase in eosinophils from shiitake mushroom powder and to search for an underlying cause.

TECHNICAL APPROACH: Five to ten subjects will take 4 grams of shiitake mushroom powder daily for up to 8 weeks and will report an symptoms that develop. Subjects will be monitored for eosinophil count at baseline and every two weeks.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Study recently approved.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-100

Prospective Comparison of the Biopsy Quality Obtained from the 16 and 18 Gauge Automated MONOPTY (BARD) Liver Biopsy Needle

START DATE: Nov 95 EST COMP DATE: Apr 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastroenterology

ASSOCIATE INVESTIGATORS: MAJ Scot Lewey, COL Jerry Sims

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Pending

FUNDING:

GIFTS:

KEY WORDS: biopsy specimens, biopsy needles

OBJECTIVE: Objective evaluation of two liver biopsy instruments.

TECHNICAL APPROACH: Randomize patients to undergo percutaneous liver biopsy with the 16 gauge or 18 gauge Bard monopty liver biopsy needle. Blinded interim analysis at n = 40 to determine if significance is achieved and to confirm best estimate of sample size using power analysis (approximately 200 to 250 patients in 18 months.) Evaluable parameters: number of portal tracts and number of central veins in the biopsy specimen.

PROGRESS:

Number of subjects enrolled to date: 20

Number of subjects enrolled for reporting period: 20

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Will continue enrollment. Will attempt to have former PI, MAJ Hammond, get IRC approval for this study at TAMC.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-101

Chest Pain Syndromes in Active Duty Females: Screening and Diagnosis

START DATE: Feb 95 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Mark Dorogy, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Jennifer Calagan, LTC, MC, Marc Cote, MAJ, MC, Mike McBiles, LTC, MC, Peter McNally, LTC, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: DWHRP \$264,500

GIFTS:

KEY WORDS: chest pain

OBJECTIVE: To establish the incidence of various etiologies of chest pain in active duty women and to improve the accuracy, efficiency, and cost-effectiveness with which we are able to confirm or exclude cardiac disease in women with chest pain, and then if cardiac pathology is eliminated, to expedite the determination and treatment of the true cause.

TECHNICAL APPROACH: Evaluate 100 women between 18 and 70 using clinical evaluations---nuclear perfusion exercise test with cardiolite, cardiac catheterization, esophagogastroduodenoscopy

PROGRESS:

Number of subjects enrolled to date: 20

Number of subjects enrolled for reporting period: 20

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): Patient #014, 21 Jul 95, pseudoaneurysm of right femoral artery

Summary of prior and current progress: Fifteen patients have completed the cardiac workup. As of 31 Jul 95 six patients have undergone some testing in gastroenterology. Multiple problems have hampered enrollment including re-assignment of many of the original investigators and FAMC's planned closure. Other study sites may be approved soon.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-102

Gastrointestinal Lesions in Iron Deficient Premenopausal Women

START DATE: Feb 95 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: James Cremins, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Thomas Kepczyk, MAJ, MC, Peter McNally, LTC, MC, Milton Smith, LTC, MC, Dirk Davis, MAJ, MC, Scot Lewey, LTC, MC, Steven Hammond, MAJ, MC, Brian Long, BS, LPN

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: DWHRP \$130,900

GIFTS:

KEY WORDS: anemia, ulcers

OBJECTIVE: Prospective evaluation of 100 premenopausal women who are found to have iron deficiency anemia.

TECHNICAL APPROACH: Volunteers will be evaluated with full colonoscopy, upper endoscopy and small bowel biopsy to evaluate for sprue.

PROGRESS:

Number of subjects enrolled to date: 1

Number of subjects enrolled for reporting period: 1

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: One subject is enrolled and four potential subjects were screened.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-103

A Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Investigate the Efficacy and Safety of Inhaled and Intranasal GG167 in the Treatment of Influenza A and B Viral Infections. IND 43,776-NAIA2005

START DATE: NA EST COMP DATE: NA STATUS: Terminated.

PRINCIPAL INVESTIGATOR: Christopher Sirridge, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Adult Primary Care

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Sponsor terminated protocol before any patients were enrolled at FAMC.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-104

A Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Investigate the Efficacy and Safety of GG167 Therapy in the Prevention of Progression of Influenza A and B Viral Infections. IND 43,776-NAIA2006.

START DATE: EST COMP DATE: STATUS: Terminated.

PRINCIPAL INVESTIGATOR: Christopher Sirridge, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Adult Primary Care

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

 Number of subjects enrolled to date:

 Number of subjects enrolled for reporting period:

 Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Sponsor terminated the study before any patients were enrolled at FAMC.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-105

Use of Ultraviolet B-exposed Skin to Detect Abnormal Cytokine Responses in Pulmonary Hypertension Patients

START DATE: Jan 95 EST COMP DATE: Mar 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Thomas McGovern, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: Scott Bennion, COL, MC, David Norris, MD, Marjorie Middleton, PhD, Norbert Voelkel, MD, David Badesch, MD, Kris Wynne, RN, Burt Groves, MD

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: cytokine, pulmonary hypertension, skin, ultraviolet radiation

OBJECTIVE: Determine differences in response to UVR between patients with and without PPH.

TECHNICAL APPROACH: Assess the level of staining of UVR-irradiated skin biopsies for various cytokines, adhesion molecules, and other histological changes.

PROGRESS:

Number of subjects enrolled to date: 9

Number of subjects enrolled for reporting period: 9

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Staining of specimens will begin soon.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-106

Screening Colonoscopy for Symptomatic Volunteers

START DATE: Jan 95 EST COMP DATE: Jan 96 STATUS: terminated

PRINCIPAL INVESTIGATOR: Milton Smith, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Xiomara I. Puckerin, CPT, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: colonoscopy, polyps

OBJECTIVE: To determine what percentage of asymptomatic Blacks have colorectal cancer or colon polyps.

TECHNICAL APPROACH: Prospective design study to enroll approximately 100 consenting Black adults, 50-75 years of age, having no risk factors associated with increased incidence of colorectal carcinoma will be included.

PROGRESS:

Number of subjects enrolled to date: 6

Number of subjects enrolled for reporting period: 6

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): none.

Summary of prior and current progress: Two subjects were found to have polyps without symptoms. Insufficient data to analyze before investigators PCS'd.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-107A

Analysis of the Effects of UVB-Irradiation of the Bone Marrow/Spleen Cell Innoculum on the Subsequent Development of Graft-versus Host Disease and Leukemic Relapse in Leukemic RF-strain Mice After Allogenic BM/SC Transplantation

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Martin Johnson, MAJ, USAF, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: Scott Bennion, COL, MC, Kathy David-Bajar, LTC, MC

PERIODIC REVIEW DATE: REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: mouse, leukemia, transplantation

OBJECTIVE: Develop a leukemic mouse model; Treat leukemic mice with bone marrow/spleen cell transplantation with and without pretreatment of the marrow/spleen cell innoculum with ultraviolet-B irradiation; Confirm the UV-B prophylactic effect on Graft-vs-Host disease; Evaluate the UV-B effect of leukemic relapse rates.

TECHNICAL APPROACH: RF mice were sublethally x-irradiated to expedite their leukemic transformation; Bone marrow/spleen cells (BM/SC) from Balb/c mice were exposed in-vitro to UV-B at varying doses to establish a dose-response curve, evaluated by in-vitro lymphocyte stimulation assays and in-vivo syngeneic BM/SC transplantation assays.

PROGRESS:

Number of subjects enrolled to date: RF-40; Balb/c-37

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Phases I.1, I.2, I.3, and I.5 are complete or in progress. To date no leukemia has arisen in the irradiated RF mice, which precludes Phases I.4, II.2, II.3 and II.4. We have established a UV-B dose-response curve and have successfully transplanted UV-B irradiated BM/SC into lethally irradiated syngeneic mice.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-108

Anaphylaxis and the School Setting: A Survey

START DATE: Feb 95 EST COMP DATE: Apr 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Martin Dubravec, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/Allergy-Imm

ASSOCIATE INVESTIGATORS: Nicholas Battafarano, MAJ, MC, Harry Spaulding, COL, MC

PERIODIC REVIEW DATE: 8 Dec 94 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: anaphylaxis

OBJECTIVE: To educate school workers on a potentially lethal syndrome in which simple, timely intervention during early stages of onset can be life-saving.

TECHNICAL APPROACH: Local school personnel will be asked to fill out a questionnaire prior to the presentation. Following the presentation, another questionnaire will be distributed to the previous respondents.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Investigators failed to provide a report for the fiscal year.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-109

Phase II Study of Single Agent Thiotepa for Advanced, Hormone-Refractory Prostate Cancer

START DATE: EST COMP DATE: STATUS: Terminated

PRINCIPAL INVESTIGATOR: Richard Tenglin, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Jan 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: To test the effectiveness and safety of thiotepa for advanced hormone refractory prostate cancer.

TECHNICAL APPROACH:

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: No patients enrolled.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-110

Serial Intradermal Vaccination with Recombinant Hepatitis B Vaccine to Seroconvert Primary Series Nonresponders

START DATE: Feb 95 EST COMP DATE: Jan 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: John Walker, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Allergy-Imm

ASSOCIATE INVESTIGATORS: Nicholas J. Battafarano, MAJ, MC;
Shashi Kumar, MAJ, MC

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: hepatitis b, vaccine, intradermal vaccination

OBJECTIVE: To determine if giving a series of intradermal Hepatitis B vaccinations will seroconvert primary series nonresponders. Essentially, we are using the Langerhan's cell as the antigen presenting cell rather than the macrophage.

TECHNICAL APPROACH: Prospective therapeutic trial.

PROGRESS:

Number of subjects enrolled to date: 5

Number of subjects enrolled for reporting period: 5

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Fifteen subject were referred for evaluation for failure to respond to the primary series of Hepatitis B immunization and five of these have qualified for intradermal injections. Ten of the 15 converted to the single intramuscular booster and were excluded from further participation. Five subjects were eligible for inclusion in the actual study with serial intradermal injections. Two of these subjects have completed participation since both seroconverted after three intradermal injections. Quantitative titers have not been determined to date.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-111

Balloon Cytology for the Detection and Surveillance of Barrett's Esophagus: A Multicenter Study

START DATE: 1 Feb 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Scot Lewey, LTC, MC

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: Barrett's esophagus, surveillance

OBJECTIVE: To compare the balloon cytology technique with conventional endoscopically obtained cytology and biopsy specimens in detecting early cancer.

TECHNICAL APPROACH: per objective

PROGRESS:

Number of subjects enrolled to date: 20

Number of subjects enrolled for reporting period: 20

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Preliminary analysis underway. Enrollment to continue.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-112

One-time Use of IND, Thalidomide, to Treat Behcet's Disease in a 20-year-old Male

START DATE: 20 Jan 95 EST COMP DATE: ? STATUS: Terminated

PRINCIPAL INVESTIGATOR: Raymond Enzenauer, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Rheum

ASSOCIATE INVESTIGATORS: None.

PERIODIC REVIEW DATE: 20 Jan 95 REVIEW RESULTS: Emergency use

FUNDING: NA

GIFTS: NA

KEY WORDS: Behcet's disease, thalidomide

OBJECTIVE: Emergency use treatment, failed all other standard modalities.

TECHNICAL APPROACH: 200 mg per day for 6 months with continued use depending on response.

PROGRESS:

Number of subjects enrolled to date: 1

Number of subjects enrolled for reporting period: 1

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Treatment discontinued after 2 weeks due to pruritic rash which improved with drug discontinuation.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-113

Comparison of Testing of Liquid Hand Dishwashing Detergent
Irritancy Using Aluminum Chamber and Standard Patch Methods

START DATE: Mar 95 EST COMP DATE: May 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Nadja Grammer-West, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: James Fitzpatrick, COL, MC

PERIODIC REVIEW DATE: 7 Mar 95 REVIEW RESULTS: Approved

FUNDING: None.

GIFTS: None.

KEY WORDS: irritancy, dishwashing liquid

OBJECTIVE: The purpose of this study was to compare the irritancy of ten common name brand dishwashing liquids and to determine if "sensitive skin" formulas were less irritating than regular ones.

TECHNICAL APPROACH: Sixteen subjects participated, four had history of atopy. The modified patch testing method entailed five consecutive exposures to dilute solutions of the dishwashing liquids with final assessment of erythema, scaling and fissuring after 72 hours.

PROGRESS:

Number of subjects enrolled to date: 16

Number of subjects enrolled for reporting period: 16

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): none

Summary of prior and current progress: Major commercially available brands of hand dishwashing liquids may vary in their ability to cause irritant dermatitis. Subjects with a history of atopy had more severe irritation, but those without a history also exhibited an irritant response. Palmolive SS caused the least irritation.

PUBLICATIONS: Comparison Testing of the Irritancy of Hand Dishwashing Liquids Using Modified Patch Testing Methods., unreported journal

PRESENTATIONS: None reported.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-114

One-time use of IND #40,592, DMP-840, to treat metastatic germ cell testicular cancer

START DATE: 14 Feb 95 EST COMP DATE: ? STATUS: Terminated

PRINCIPAL INVESTIGATOR: Scott Kruger, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 14 Feb 95 REVIEW RESULTS: Emergency use

FUNDING: NA

GIFTS: NA

KEY WORDS: cancer

OBJECTIVE: Treatment when all standard treatments have failed.

TECHNICAL APPROACH: Continuous infusion based on weight.

PROGRESS:

Number of subjects enrolled to date: 1

Number of subjects enrolled for reporting period: 1

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Treatment failure.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-115

A Double-Blind, Multicenter, Parallel Study Comparing the Efficacy and Safety of Oral Granisetron Hydrochloride 2 mg with Intravenous Ondansetron Hydrochloride 32 mg Given Once Prior to Chemotherapy in the Prevention of Nausea and Vomiting Induced by Cisplatin-based Chemotherapy. (BRL43694A/341) IND#33,651

START DATE: Apr 95 EST COMP DATE: ? STATUS: Terminated

PRINCIPAL INVESTIGATOR: Richard Tenglin, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 7 Mar 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Study terminated by sponsor before patient enrollment at FAMC.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-116

3TC Open Label Protocol NUCA3004 including Amendment 6,
IND #37,158

START DATE: 7/13/95 EST COMP DATE: 4/30/96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Donald Skillman, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Infect Dis

ASSOCIATE INVESTIGATORS: None

PERIODIC REVIEW DATE: 4 Apr 95 REVIEW RESULTS: Approved

FUNDING: None

GIFTS: Drug supplied by Glaxo

KEY WORDS: HIV, 3TC

OBJECTIVE: To determine if 3TC or 3TC in combination with AZT
affects progress of HIV disease.

TECHNICAL APPROACH: Per protocol.

PROGRESS:

Number of subjects enrolled to date: 2

Number of subjects enrolled for reporting period: 2

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None at FAMC

Summary of prior and current progress: Patients with fewer than
100 CD4 cells receive priority to get drug - only 350
patients/week entered into program.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-117

Efficacy of Portable Ultrasound Guided Paracentesis

START DATE: 1 Mar 95 EST COMP DATE: 1 Jul 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Jack DePriest, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Pul

ASSOCIATE INVESTIGATORS: George Winter, CPT, MC

PERIODIC REVIEW DATE: 4 Apr 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: ultrasound, ascites

OBJECTIVE: To determine if a portable ultrasound unit can reliably identify the presence of abdominal fluid that is amenable to paracentesis.

TECHNICAL APPROACH: Twenty patients scheduled for ultrasound to evaluate for ascites will have portable ultrasound at bedside and a determination made whether there is ascitic fluid that could be tapped at the bedside (yes or no). This will be compared with results of the formal radiologic study.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): 0

Summary of prior and current progress: No progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-118

Transesophageal Echocardiography for Assessment of Thrombus in Postoperative Atrial Fibrillation

START DATE: Aug 95 EST COMP DATE: Aug 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: David Schachter, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Mark Dorogy, MAJ, MC

PERIODIC REVIEW DATE: 6 June 95 REVIEW RESULTS: Approved

FUNDING: None.

GIFTS: None.

KEY WORDS: transesophageal echocardiography, thrombus, atrial fibrillation

OBJECTIVE: To describe the incidence of AAT during postoperative AF.

TECHNICAL APPROACH: TEE will be performed on PO subjects and blood analyzed for clotting proteins and platelet function.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): 0

Summary of prior and current progress: No progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-119

Assessment of Illness Experience and Informational Needs of Patients

START DATE: Jun 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Susan Drake, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med

ASSOCIATE INVESTIGATORS: James Hanley, COL, MC, Leslie Tuchmann, CPT, AN

PERIODIC REVIEW DATE: 6 June 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: terminal diseases, decision making

OBJECTIVE: To describe the informational needs and readiness to make particular decisions of patients with terminal diseases.

TECHNICAL APPROACH: This is Dr. Jean Kutner's protocol at UCHSC. The pilot phases are complete. FAMC will participate in the bulk of the study to enroll the 100 patients in Phase II, Stage 3. Questionnaires and audio taping will be used.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: Investigators failed to provide a progress report for the fiscal year.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-120

Colorado Collective for Medical Decisions - Guidelines for the Use of Intensive Care in Denver (GUIDe)

START DATE: Apr 95 EST COMP DATE: Apr 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Jennifer Hill, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med

ASSOCIATE INVESTIGATORS: James Hanley, COL, MC, Teresa Mason, LTC, MC, Susan Drake, CPT, MC

PERIODIC REVIEW DATE: 6 Jun 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS:

OBJECTIVE: To more clearly define inappropriate intensive care and to determine guidelines for the utilization of intensive care.

TECHNICAL APPROACH: Survey

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: Investigators failed to provide a report.

PUBLICATIONS: ?

PRESENTATIONS: ?

To date the IRC's stipulations for approval are not accomplished.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-121

A Study to Evaluate the Effects of Therapy with Lansoprazole and Clarithromycin and/or Amoxicillin on the Eradication of Helicobacter pylori. IND 44,219/44,532/47,829/M95-282.

START DATE: Sep 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Gastro/Med

ASSOCIATE INVESTIGATORS: James Cremins, MAJ, MC, James Egan, MAJ, MC, Scot Lewey, LTC, MC, Brian Long, BS, LPN

PERIODIC REVIEW DATE: 1 Aug 95 REVIEW RESULTS: Approved
FUNDING: ?

GIFTS: TAP Holdings will provide drugs and placebo in blinded form and supplies to ship specimens to central lab.

KEY WORDS: ulcer, Lansoprazole, Clarithromycin, Amoxicillin, Helicobacter pylori

OBJECTIVE: This phase III study is designed to compare the safety and efficacy of monotherapy with lansoprazole, dual therapy with lansoprazole and amoxicillin or lansoprazole and clarithromycin, and triple therapy with lansoprazole, clarithromycin and amoxicillin for the eradication of Helicobacter pylori from the gastric mucosa of patients with duodenal ulcer.

TECHNICAL APPROACH: Multicenter, blinded, four arm protocol. Approximately 5-10 subjects to be enrolled at FAMC.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Recently approved by IRC, pending CIRO approval.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-122

Use of Venous Oximetry to Confirm Proper Pulmonary Artery Catheter Placement

START DATE: Aug 95 EST COMP DATE: Sep 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Jack L. DePriest, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Pul

ASSOCIATE INVESTIGATORS: None.

PERIODIC REVIEW DATE: 9 Aug 95 REVIEW RESULTS: Exempt

FUNDING: NA

GIFTS: NA

KEY WORDS: oximetry, catheter placement

OBJECTIVE: To determine whether looking for a 10% step-up in mixed venous oxygen saturation impacts on daily management decision.

TECHNICAL APPROACH: As part of routine patient rounds data was collected focusing on two issues. First, what was the pattern of change in SVO2 seen during balloon occlusion of the pulmonary artery in critically ill patients. Secondly, if one fails to see a 10% step-up on initial occlusion and by manipulation of the catheter does obtain a subsequent acceptable step-up, is there a clinically significant difference between the two wedge measurements.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: In summary, critically ill patients demonstrate a wide range of changes in SVO2 as determined by oximetry when the pulmonary artery is occluded. The amount of step-up seen can be increased by performing simple manipulations of the catheter. However, while documenting a step-up in SVO2 may be considered supportive of Zone III placement, it is not possible to describe any cut-off values that ensure correct positioning. If one wants to document catheter arterialization of wedged blood to confirm Zone III catheter placement, they should obtain an aspirated sample and follow previously defined criteria.

PUBLICATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-123

Phase I/II Study of Hydroxychloroquine for Human Immunodeficiency Virus (HIV) Infection.

START DATE: Oct 95 EST COMP DATE: Mar 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Timothy Murphy, CPT, MC

FACILITY/DEPT/SVC: FAMC/Infect Dis/Med

ASSOCIATE INVESTIGATORS: Donald R. Skillman, LTC, MC, David Zumbro, CPT, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: HIV, hydroxchloroquine

OBJECTIVE: Determine safety and efficacy of HCQ in HIV-infected persons; determine effects of HCQ on quantity of circulating HIV-1, as measured by quantitative PCR; determine effects of HCQ on CD4+ T lymphocyte vales and circulating p24 Antigen; acquire blood samples for possible later determination of the effects of HCQ on development of resistance to RT inhibitors (Specific codon mutations); acquire cell samples for possible future studies to determine the molecular mechanism of any observed anitviral effects.

TECHNICAL APPROACH: Unblinded pilot study to determine if in vitro anti-HIV effects of HCQ can be reproduced in human subjects.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Recently approved by IRC.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR SOUTHWEST ONCOLOGY GROUP PROTOCOLS

90/126 SWOG 8710	91/102 SWOG 8894	93/107 SWOG 9030
90/129 SWOG 8814	91/103 SWOG 8906	93/109 SWOG 9148
90/138 SWOG 8520	91/104 SWOG 8925	93/116 SWOG 9008
90/140 SWOG 8692	91/118 SWOG 9013	93/117 SWOG 9119
90/141 SWOG 8711	91/119 SWOG 9038	93/119 SWOG 9216
90/142 SWOG 8736	91/133 SWOG 9111	93/122 SWOG 9003
90/144 SWOG 8794	91/150 SWOG 9007	93/123 SWOG 9031
90/146 SWOG 8809	91/151 SWOG 9108	93/124 SWOG 9032
90/147 SWOG 8819	92/101 SWOG 8913	93/125 SWOG 9133
90/158 SWOG 8851	92/102 SWOG 8956	93/132 SWOG 9034
90/159 SWOG 8892	92/122 SWOG 9061	93/133 SWOG 9104
90/164 SWOG 8952	92/143 SWOG 9035	93/134 SWOG 9143
90/176 SWOG 8994		

START DATE: 1980 EST COMP DATE: STATUS: TERMINATED

PRINCIPAL INVESTIGATOR: DANIEL TELL, LTC, MC

FACILITY/DEPT/SVC: FAMC/MED/HEM-ONC

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: JAN 95 REVIEW RESULTS: TERMINATED
FUNDIBNG: NA
GIFTS: NA

KEY WORDS: CANCER

OBJECTIVE: CANCER TREATMENT

TECHNICAL APPROACH: PER NCI PROTOCOL.

PROGRESS: SINCE THE ELIMINATION OF THE ONCOLOGIST DATA MANAGER'S POSITION AT FAMC A NUMBER OF YEARS AGO, NO NEW SUBJECTS WERE ENROLLED. THE PREVIOUS PI REQUESTED THAT THE STUDY BE PLACED "ON HOLD", AND THE IRC AGREED TO THE HOLD STATUS FOR A PERIOD NOT TO EXCEED ONE YEAR. NO PATIENTS ARE ON ACTIVE TREATMENT.

Detail Summary Sheet

(1) Date: 24 Jul 95 (2) Protocol #: 90/204 (3) Status: Completed

(4) Title: A Clinical Comparison of a Hydroxylapatite Coated Versus
Porous Coated Total Hip Implant for Use in Arthritic
Human Hips

(5) Start Date: 1990

(6) Est Compl Date: 1996

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
Paul Castello, CPT, MC

(11) Key Words:
hydroxyapatite

Frederick Coville, COL (RET)

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 96

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Compare results of two porous ingrowth hip components to improve amount of ingrowth, thereby, reduce the need for revisions.

(16) Technical Approach: Posterior approach to the hip routine implantation of a porous femoral/acet. component.

(17) Progress: Hip scores on hydroxy apatite hips is consistently higher than the non HA coated hip. HA hip scores run about 8 points higher than non HA for same time period. No adverse reactions to the HA coating have been found. FY94: Study on hold due to lack of inventory (at manufacturer's end). Study will proceed when inventory problems are solved. FY95: We are in the process of reviewing clinical charts and radiographs of all participants in this study. As soon as we are finished, then we will summarize and present our findings. No new patients will be added.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 92/202A (3) Status: Completed

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: 1991 (6) Est Compl Date: 1996

(7) Principal Investigator: Royal K. Gerow, LTC, MC (8) Facility: FAMC

(9) Dept of SURG/Plastic Surg. (10) Associate Investigators

(11) Key Words:
microvascular surgery
free flaps, rats

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____ 20 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To instruct plastic surgery fellows and staff in microvascular surgery and attain and maintain proficiency.

(16) Technical Approach: With anesthetized rats, the femoral artery and veins will be divided and then anastomized using microvascular techniques.

(17) Progress: Integral training of 2 plastic surgery fellows and maintaining proficiency of 4 plastic surgery staff.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 92/204 (3) Status: Terminated

(4) Title: Effect of Intravenous Erythromycin on Postoperative Ileus

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Joseph Kolb, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen. Surg.

(10) Associate Investigators

(11) Key Words:

Dr. Hollis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if erythromycin helps resolve post operative ileus.

(16) Technical Approach: This is a randomized, double-blind study.

(17) Progress: Awaiting randomization of specimens. The project is, in essence, ready to begin.

FY94: Study well underway. Ready to evaluate initial data with eight more patients. FY95: To date 20 subjects enrolled, need 10 more. Don't have the personnel to continue this study.

Publications and Presentations: None

Detail Summary Sheet

- (1) Date: 6 Jun 95 (2) Protocol #:92/206 (3) Status: Completed
- (4) Title: Intraocular Liquid Silicone for Complicated Retinal Detachments. (IDE)
- (5) Start Date: 1992 (6) Est Compl Date: 1995
- (7) Principal Investigator: William Waterhouse, MAJ, MC (8) Facility: FAMC
- (9) Dept/Svc: Ophthalm/Surg. (10) Associate Investigators:
- (11) Key Words: silicone oil Robert Dragoo, COL, MC
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
- (14) a. Date, Latest IRC Review: June/Jan b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
- (15) Study Objective: Clinical trial of intraocular liquid silicone for treatment of complicated retinal detachments.
- (16) Technical Approach: See protocol.
- (17) Progress: 6-month review. Two additional patients were enrolled for a total of ten. FAMC remains the only Army treatment facility which has the ability to treat complicated retinal detachments with silicone oil, thanks to this ongoing protocol. This is a valuable treatment protocol for our patients. FY95: FDA approved drug.

Publications and Presentations: None.

Detail Summary Sheet

-
- (1) Date: 3 Jan 95 (2) Protocol #: 92/207 (3) Status: Ongoing
-
- (4) Title: Vivonex Ten Versus Immun-Aid in a SICU Population:
Effects on Restoring Normal Protein Markers
-
- (5) Start Date: 1992 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Sharon Hammond, LTC, MC (8) Facility: FAMC
-
- (9) Dept of SURG/Gen.Surg. (10) Associate Investigators
-
- (11) Key Words: protein markers enteral formulas Dr. Mallory
Joan Friend
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".
-
- (15) Study Objective: Compare two enteral formulas in respect to
nutritional aspects.
- (16) Technical Approach: Protocol will take place in SICU.
- (17) Progress: Nine patients were enrolled with five completed.
Protocol will continue until between 10-20 subjects are enrolled.
F95: Fourteen patients entered into the protocol with only three
completing. There has been multiple reasons for patients not
completing. These include administration of albumin during testing,
intolerance of tube feeding, malfunction of jejunostomy tube and ileus
(prolonged). We are continuing to enroll patients into the protocol with
a goal to obtain ten patients to perform power analysis.
- Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: 7 Feb 95 (2) Protocol #: 92/208 (3) Status: Completed
-
- (4) Title: Response of Serum Cytokines in Patients Undergoing Laparoscopic Cholecystectomy to Support the Use of Laparoscopic Techniques for Other Surgery
-
- (5) Start Date: 1992 (6) Est Compl Date: 1994
-
- (7) Principal Investigator: John Cho, CPT, MC (8) Facility: FAMC
-
- (9) Dept of SURG/Gen. Surg. (10) Associate Investigators
Dallas Homas, CPT, MC
Jeffrey Clark, COL, MC
Matthew Schofield, CPT, MS
Sharon Hammond, MAJ, MC
-
- (11) Key Words: cytokines
cholecystectomy
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To demonstrate that the clinical benefits seen in minimally invasive laparoscopic gallbladder surgery versus open cholecystectomy result from a lack of cytokine release leading to attenuation of the acute phase response.
- (16) Technical Approach: Measuring 11-6 the acute phase protein-C-reactive protein- and demonstrating a correlation between and a diminution of cytokine and APP release in laparoscopic versus open cholecystectomy should prove this point.
- (17) Progress: Eleven patients enrolld out of 20. Blood being analyzed on six or seven more. Study is almost complete.
- FY94: Expect to complete the study by April, 1994. Ten additional subjects enrolled for a total of 25.

Publications: None.

Presentations: 1994 SAGES meeting; poster presentation at the American College of Surgeons 1994 Sept. meeting.

Detail Summary Sheet

- (1) Date: 5 Sep 95 (2) Protocol #: 92/209 (3) Status: Ongoing
- (4) Title: A Randomized Study of the Stryker OP Device vs Bone Autograft for the Treatment of Tibial Non-Unions
- (5) Start Date: 1992 (6) Est Compl Date: 1995
- (7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC
- (9) Dept of SURG/Orthopedics (10) Associate Investigators Paul Castello, CPT, MC
- (11) Key Words: non union BMP, IDE
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: MAR/SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 1 _____
d. Total Number of Subjects Enrolled to Date: _____ 9 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: To increase the rate of healing of tibial non unions.
- (16) Technical Approach: Non union debridement either use crest graft or OPI.
- (17) Progress: Two additional patients enrolled for a total of three. 6-month review: No new patients enrolled. To qualify for study, tibial fractures must fail to unite for 9 months and patients must meet strict qualifying guidelines. The investigators have been in communication with other military hospitals who are cooperating with us to locate potential candidates.
FY94: No adverse events have occurred in the six subjects enrolled to date. Sep 94: FDA recently approved a supplement to the investigational device exemption application. Patients with partial neuropathy may now be included for study; patients with complete neuropathy will be excluded.
FY95 Mar: Two additional patients were enrolled into the study for a total of 8. The indications and quantifications remain stringent, and we are still seeking patients from other military treatment facilities. No adverse events have occurred to date in 8 patients. Sep 95: One additional patient enrolled. Patient #9 had an adverse event--infected autograft.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 92/210A (3) Status: Completed

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair in Rabbits and Rats

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Glen Yoshida, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/Otolaryn

(10) Associate Investigators

(11) Key Words:

microsurgical anastomosis, free flalp, small blood vessel repair, never repair

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IACUC Review: MAR b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 4rats

d. Total Number of Subjects Enrolled to Date: 16

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Training of Oto-HNS residents, staff in microsurgical techniques for nerve and vessel repair.

(16) Technical Approach: Transection and repair of femoral nerve, artery, vein of the rat/rabbit utilizing microsurgical techniques.

(17) Progress: Maintenance of microsurgical proficiency has been achieved. Over this period 2 residents received 6 hrs of training.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 92/212 (3) Status: Completed

(4) Title: The Incidence and Association of Carpal Ligamentous Injuries with Distal Radius Fractures

(5) Start Date: 1992

(6) Est Compl Date: 1995

(7) Principal Investigator:
John Reiser, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
LTC D.E. Casey Jones, MC
MAJ Kevin Rak, MC
MAJ Bernard Borosky, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 19

d. Total Number of Subjects Enrolled to Date: 50

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the incidence of carpal ligament injury with distal radial and ulnar fractures. Additionally, we will determine the association between the incidence of carpal ligament injury and the classification on severity of distal forearm fractures.

(16) Technical Approach: Data from MRI and radiographic evaluations will be compiled as to severity and classification of the fractures. This data will be analyzed statistically for an association of ligaments injury with distal radial and ulnar fractures, and the incidence with which this association occurs. Carpal ligament injury will be analyzed for association with severity on classification of distal radial and ulnar fractures.

(17) Progress: Twenty-two patients have completed the study. project ongoing. FY94: Over 40 patients now entered in study. Preliminary data was presented at the annual meeting of the American Academy of Orthopedic Surgery in Mar 94. We are currently writing up the data available for submission for publication. an abstract of the data will appear in Orthopedic Transactions this year. Request that the protocol remain open for ongoing data collection.
FY95: Plan to submit for publication.

Publications and Presentations: Presented at the National Hand Surgery Symposium.

Detail Summary Sheet

(1) Date: 6 Jun 95 (2) Protocol #: 92/213 (3) Status: Completed

(4) Title: Efficacy of Percutaneous Release of the Trigger
Finger: An Anatomic Study

(5) Start Date: (6) Est Compl Date: 1995

(7) Principal Investigator: (8) Facility: FAMC
Steven Friedel, CPT, MC

(9) Dept of SURG/Orthopedics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To anatomically check the efficacy of the
percutaneous release.

(16) Technical Approach: A percutaneous release will be followed by a
standard open release (to determine if the percutaneous release has
completely divided the A1 pulley).

(17) Progress: 17 releases have been performed using this protocol. We
anticipate doing a power study of our data at 30 cases.

FY94: The study was amended in Jan 94 to add an arm to the study.
Working on publishing report for first part and collecting data on the
second part.

FY95: All subjects have been enrolled. Paper is being prepared for
submission to Journal of Hand Surgery.

Publications: None

Presentations: Preliminary data will be presented at the Summer meeting
of the Western Orthopaedic Association, July 1993, and the Academy of
Surgical Research Annual Meeting, September 1993.

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 92/215 (3) Status: Completed

(4) Title: Comparison of Three Pneumatic Compression Devices in 300 Total Hip and Knee Replacement Patients.

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURG/Orthopedics (10) Associate Investigators
Mark Clyde, CPT, MC
Brad Nelson, CPT, MC

(11) Key Words: pneumatic compression devices

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 66
d. Total Number of Subjects Enrolled to Date: 196
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine which three pneumatic compression devices is most effective in preventing DVT.

(16) Technical Approach: Patients will be randomly assigned to one of three pneumatic compression devices following total hip or total knee replacement. Patients will be monitored for clinical signs of DVT. Also, patients will undergo doppler ultrasound if DVT are suspected, or on their 10-14th day post-op.

(17) Progress: FY93: Study is now underway with 43 patients enrolled to date. FY94: 130 patients enrolled to date. Sep 94: Enrollment ongoing. Winner of Barnard and Hugh Mahon Contests, 1994. FY95: Study has been completed. Will be submitted for publication in Journal of Arthroplasty.

Publications: None.

Presentations: Barnard and Hugh Mahon Contests, 1994.
Poster exhibit accepted for presentation to the American Academy of Ortho Surgeons, Feb 95.

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 92/216 (3) Status: Completed

(4) Title: Comparison of Three Postoperative Autologous Blood Transfusion Techniques (Haemonetics Cell Saver, AUTOVAC LF System, and Stryker ConstaVac System) in 300 Total Hip and Knee Replacements

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Steven Friedel, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Ortho

(10) Associate Investigators

(11) Key Words:

Edward J. Lisecki, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep/Mar b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 150
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare three methods of postoperative autologous blood transfusion. Methods will be compared for; amount of blood recovered/reinfused; amount of blood bank transfusions required; hemolysis of collected blood product, bacterial contamination of collected blood product; febrile reactions; fat embolism syndrome.

(16) Technical Approach: 300 patients will be randomly assigned to one of three methods of postop autologous blood transfusion following total hip or totoal knee replacement.

(17) Progress: Study ongoing. FY94: Study proceeding according to plan. FY95 March: To date 150 patients enrolled. Sep 95: Completed and manuscript submitted for possible publication in the Journal of Arthroplasty.

Publications: None.

Presentations: Winner of Barnard & Hugh Mahon Contests, 1994.
AAOS, Feb 95.

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 92/218A (3) Status: Completed

(4) Title: Effect of Nicotine on Bone Ingrowth and Fixation in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Michael P. Grant, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Ortho (10) Associate Investigators

(11) Key Words: LTC Edward Lisecki, MC
Stephen D. Cook Ph.D.
MAJ Bert Callahan, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____7_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify the biomechanical and histological effects of nicotine on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Twenty goats will be randomly assigned to type of treatment (21 mg nicotine/day or control). Four rods which are HA coated for 1/2 of their length will be placed into each femur of each goat. Following euthanasia at 3,6,12,26, or 52 weeks, the implants will be removed and tested for bony ingrowth and fixation strength.

(17) Progress: Initial study has revealed problems with nicotine delivery system. We are investigating possibilities for alternate delivery.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 93/202A (3) Status: Completed

(4) Title: Vascular/General Surgery Staff and Resident Training Using Laparoscopic Techniques in the Swine (Sus scrofa)

(5) Start Date: 1993

(6) Est Compl Date:

(7) Principal Investigator:
Sharon L. Hammond, MAJ, MC

(8) Facility: FAMC

(9) Dept of SUR/Gen.Surgery

(10) Associate Investigators
Dr. Philip Mallory

(11) Key Words:
laprascopic surgery

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To train residents and staff on the technical aspects of laparoscopic surgery prior to human application.

(16) Technical Approach: Animal model - Appropriate with laparoscopic surgery.

(17) Progress: Have had recent animal lab with pig - was well attented with good training.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 93/205A (3) Status: Terminated

(4) Title: Comparison of Three Sizes of Interference Screws for Graft Fixation of the Central One-Third of the Patellar Tendon in Anterior Cruciate Ligament Reconstruction

(5) Start Date: 1993

(6) Est Compl Date:

(7) Principal Investigator:
Jack McBride, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho

(10) Associate Investigators

Michael Grant, CPT, MC

(11) Key Words:

Richard Sherman, LTC, MS

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 20 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare three different sizes of interference screws for graft fixation of the central one-third of the patellar tendon in ACL reconstruction; to compare cannulated versus noncannulated screws for graft fixation of the central one-third of the patellar tendon in ACL reconstruction.

(16) Technical Approach: Three groups of six goats will be used; groups will be divided based on size of interference screws. A patellar graft will be harvested in bone-tendon-bone construct, placed into a bony tunnel in the tibia, and held in place by an interference screw, using an endoscopic interference technique. After the graft is fixed in place, pull-out strength will be established.

(17) Progress: An excess number of tendon ruptures occurred due to the repeated thawing and refreezing of specimens. (Thawing and refreezing were required due to time constraints in performing the procedures). Plan to memo the IACUC to request 30 more specimens on which the study can be repeated without repeated thawing and freezing. FY95: This was done by Brown, et al.

Publications and Presentations: Abstract in J. Invest Surg 6(4):370, 1993.

Detail Summary Sheet

(1) Date: 1 Nov 95 (2) Protocol #: 93/208 (3) Status: Terminated

(4) Title: ^{99m}Tc-HMPAO Labeled Leukocyte Scintigraphy in the Evaluation of Hemodialysis Access PTFE Grafts

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: Daniel Clark, CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Gen.Surg. (10) Associate Investigators
Margaret L. Clark, CPT, MC
Sharon L. Hammond, MAJ, MC
Michael McBiles, LTC, MC
Morakinyo Toney, LTC, MC

(11) Key Words:
hemodialysis grafts
scintigraphy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the efficacy of ^{99m}Tc-HMPAO leukocyte scintigraphy in evaluating hemodialysis access grafts.

(16) Technical Approach: Per protocol.

(17) Progress: At present, two subjects have been studied with no adverse effects. Administratively terminated due to noncompliance with regulations.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Nov 95 (2) Protocol #: 93/209 (3) Status: Completed

(4) Title: The Determination of the Amount of Lumbar Root Decompression After Hemilaminotomy and Foraminotomy Versus After Discectomy Using Somatosensory-Evoked Potentials

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Paul Castello, CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho. (10) Associate Investigators
MAJ Howard Place
MAJ Gary Simonds
MAJ Steven R. Shannon
CPT Robert Williamson

(11) Key Words:
lumbar root decompression
hemilaminectomy
foraminotomy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 30
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify the lumbar nerve root decompression using SSEP after discectomy, after hemilaminectomy and foraminotomy, and after the combination of the two in consenting patients with herniated lumbar discs who meet the standard objective criteria for surgical treatment.

(16) Technical Approach: Patients will be randomly assigned into two groups. Group 1 will undergo hemilaminotomy and foraminotomy followed by partial excision of the disc. Group 2 will undergo the same procedure in reverse order. Each patient will undergo preoperative, continuous intraoperative, and postoperative SSEP monitoring.

(17) Progress: Study in progress. Results to date show that bony decompression of the neural root is of prime importance when performing nerve root decompression for lumbar herniated nucleus pulposus.
FY95: Completed.

Publications: none.

Presentations: Western Orthopedic Assoc. Snowmass, CO, July 1993.
Society of Military Orthopaedic Surgeons, 1995.

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 93/210A (3) Status: Completed

(4) Title: An Attempt at Differentiation of Malignant Glial Cell Tumors in Rattus Norvegicus: A Pilot Study

(5) Start Date: 1993

(6) Est Compl Date: 1995

(7) Principal Investigator:
Harold B. Vogel, M.D.

(8) Facility: FAMC

(9) Dept of SUR/NeuroSurg.

(10) Associate Investigators

(11) Key Words:
brain tumor, differentiation

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____ 45 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Attempt at differentiation of malignant glial tumors in tissue culture by growing them in media which had originally supported the growth of fetal glia.

(16) Technical Approach:

(a) ensure induction of tumors in newborn rats (completed);
(b) growth of fetal glia in tissue and culture and collection of media (completed); (c) growth of rat brain tumors in tissue culture media obtained in (b), being done; (d) measurement of change by alternation of flow cytometry and tumor keryotype before and after testing with media obtained in (b), (will follow c).

(17) Progress: All rat experimentation concluded 18 Apr 94. No additional rats purchased during FY94. FY95: Protocol followed as planned. It was found, however, that the premise of the experiment was invalid and a pilot experiment was set up to see if differentiation could be brought about by exposing tumor cells in culture to 1640 media + 20% fetal cell serum +2% DMSO. This did seem to bring about differenitiation of the cells temporarily, as measured by disappearance of tumor anenploid peaks on flow cytometry, and led to submission of a new protocol, "The Differentiation of Rat Brain Tumors by Placental Lactogen in Rattus Norvegicus".

Publications and Presentations: Abstract presentation at American Association of Neurological Surgeons meeting, 4/96.

Detail Summary Sheet

- (1) Date: 6 Dec 95 (2) Protocol #: 93/211 (3) Status: Terminated
- (4) Title: Effect of Proximal Femoral Cerclage Cable in Femoral Hip Prosthesis Micromotion: A Cadaveric Study
- (5) Start Date: 1993 (6) Est Compl Date: 1994
- (7) Principal Investigator: David Kim, CPT, MC (8) Facility: FAMC
- (9) Dept of SURGERY/Ortho. (10) Associate Investigators
- (11) Key Words:
cerclage wire LTC Edward Lisecki, MC
hip prosthesis Robert Brown
micromotion
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: To assess if there is any decrease in micromotion of the bone-prosthesis interface after the application of a dall mile cerclage wire.
- (16) Technical Approach: Ten proximal femoral cadaveric stems will be examined to insure there are no structural defects. Ten LSF prosthesis will be placed according to manufacturer recommendations. Micromotion will be tested using the instron device in axial and torsional load. Dall mile cerclage wire will be placed and testing will be repeated.
- (17) Progress: Results to date show that cerclage wire does not decrease or increase the amount of motion in the constructs.
FY94: No progress. Waiting for machine parts to be able to test added dimensions. FY95: Too many problems to continue. Equipment delays and problems obtaining cadaver parts.
- Publications and Presentations: Acad of Surg Research (Breckenridge, CO, 30 Sept -2 Oct 93); Barnard Competition, Mar 93.

Detail Summary Sheet

(1) Date: 3 Jan 95 (2) Protocol #: 93/212 (3) Status: Completed

(4) Title: Vacuum Therapy Versus Intracavernous Autoinjection of Vasoactive Drugs as the Treatment for Erectile Dysfunction in Diabetic and Anti-Coagulated Patients: A Study of Satisfaction and Safety

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Jerome Limoge, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Urology (10) Associate Investigators
LTC Diane Henderson
CPT Eric Olin

(11) Key Words:
impotence
vacuum therapy
intracavernous
anticoagulation

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Safety and satisfaction of injection (intracavernous) and vacuum therapy.

(16) Technical Approach: Patients use ICI or vacuum therapy for 12 weeks each. Diaries are kept, questionnaires completed each 4 weeks.

(17) Progress: To date 35 subjects were enrolled, 9 this report period. Ten patients who tried both therapies decided not to continue in the study. Of the 25 who crossed over, 13 have completed the study.
FY95: Twenty six patients completed the study.

Publications:

Presentations: Am Ur Society, May 94, San Francisco;
International Impotence Society, Sidney;
World Congress of Urology, Singapore.

Detail Summary Sheet

(1) Date: 7 Mar 95 (2) Protocol #: 93/214 (3) Status: Ongoing

(4) Title: Comparison of the ORTHOLOC ADVANTIM Total Knee System VS the ORTHOLOC ADVANTIM Non-Cemented Total Knee System VS the ORTHOLOC ADVANTIM Hydroxylapatite Coated Total Knee System

(5) Start Date: 1993 (6) Est Compl Date: 1996

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho. (10) Associate Investigators William Pace, CPT, MC

(11) Key Words:
total knee replacement CPT Paul Castello
hydroxyapatite
cement

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 30
d. Total Number of Subjects Enrolled to Date: 30
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the safety and efficacy of the cementless use of the ortholoc advantin total knee system, with and without HA coating.

(16) Technical Approach: 480 patients will be studied nationwide. 160 will be assigned to the cementless HA device. 160 will be assigned cementless non-HA-coated device, and 160 will be assigned to the cemented device. At FAMC, 40 patients will be assigned to the HA-coated/non HA coated devices.

(17) Progress: Waiting for FDA to assign and IDE #.
FY94: FDA approved the study on 18 Feb 94.
FY95: Study is ongoing. Data has not yet been analyzed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 24 Jul 95 (2) Protocol #: 93/215 (3) Status: Terminated

(4) Title: Comparison of Femoral Hip Prosthesis Micromotion Between Eight Types of Prosthetic Devices: A Cadaveric Study

(5) Start Date: 1993 (6) Est Compl Date: Jun 1996

(7) Principal Investigator: CPT David Kim, MC (8) Facility: FAMC

(9) Dept of SURGERY/Orthr. (10) Associate Investigators Edward Lisecki, LTC, MC

(11) Key Words:
hip prosthesis
micromotion

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the amount of micromotion at the bone-prosthesis interface when using 8 different femoral prosthetic devices.

(16) Technical Approach: 40 proximal cadveric femoral stems will be randomly assigned to one of 8 groups of prosthesis types. Prosthesis will be placed according to manufacturer recommendations. Micromotion will be tested using Instron axial, rotational, side to side loads.

(17) Progress: No progress to date 2 Sept 1993. FY94: Need devices that will measure 6° of motion. (We can only measure 2°.) Devices are expected soon. FY95: No progress due to problems obtaining strain gauge and cadaver specimens.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 93/216A (3) Status: Ongoing

(4) Title: Effect of Ketolorac on Bone Healing Following Simulted Fracture in the Stauffland White Rabbit (*Oryctolagus Cuniculi*)

(5) Start Date: 1993 (6) Est Compl Date: 11/95

(7) Principal Investigator: Bradley J. Nelson, CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (10) Associate Investigators
Howard Place, MAJ, MC
Bert Callahan, MAJ, MC
Edward Lisecki, LTC, MC

(11) Key Words: bone healing

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____42_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effect of ketolorac on fracture healing in the rabbit.

(16) Technical Approach: 30 rabbits will be assigned to 1 of 3 treatment groups, (high dose ketolorac, low dose ketolorac, or control). A simulated fracture will be made in the right leg of each rabbit. Rabbits will undergo euthanasia at 35 days postop. Femurs will be collected and will undergo mechanical testing.

(17) Progress: Final surgeries were performed in July 1994. After these animals are sacrificed, data analysis will be performed. FY95: All animals sacrificed. Need to do biomechanical studies/histology.

Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: 30 Sep 95 (2) Protocol #: 93/221A (3) Status: Ongoing
-
- (4) Title: Effect of Nicotine on Soft Tissue Ingrowth and Fixation in a Hydroxyapatite Globe in a Goat Model (Capra hircus)
-
- (5) Start Date: 1993 (6) Est Compl Date:
-
- (7) Principal Investigator: Margaret Lisecki, MAJ, MC (8) Facility: FAMC
-
- (9) Dept of SUR/Ophthalmology (10) Associate Investigators
Stuart R. Farris, MAJ, MC
Edward Lisecki, LTC, MC
Stephen Cook
-
- (11) Key Words:
hydroxyapatite orbit implant
nicotine
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date: 10_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: Assessment of vascularization with and without nicotine.
- (16) Technical Approach: Control aspect of study progress.
- (17) Progress: 2 pilot animals, 1 control. FY95: Nicotine delivery system pending. Dr. Cook, in New Orleans, has processed controls for histopathology. He is also assessing possibility of delivering nicotine to animals by mask.
- Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 93/222 (3) Status: Terminated

(4) Title: Treatment of Degenerative Spondylolisthesis: A Prospective Comparison of Uninstrumented Posterior Spine Fusion with Decompression, Anterior-Posterior Instrumented Spine Fusion with Decompression, and Instrumented Posterior Spine Fusion with Decompression

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Howard Place, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho. (10) Associate Investigators

MAJ John Dietz, MC

(11) Key Words:
degenerative spondylolisthesis
spine fusion
decompression

MAJ David Polly, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare 3 surgical methods used to treat degenerative spondylolisthesis in terms of complication rate, long-term relief.

(16) Technical Approach: 50 patients will be randomly assigned to one of three surgical treatments for degenerative spondylolisthesis. Preoperative and postoperative questionnaires will be used to determine which treatment, if any, provides the best long-term relief of symptoms and the least complications.

(17) Progress: Three patients are considering entry into the study. FY94: No progress. FY95: No patients have been entered. PI will leave FAMC this summer.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Aug 95 (2) Protocol #: 93/224 (3) Status: Terminated

(4) Title: Control of Swelling After Hand and Foot Surgery for Fractures, Long Bone Fracture Stabilization, and Ankle Sprains Using Pulsed, High Frequency Electromagnetic Energy

(5) Start Date: 1993

(6) Est Compl Date: 1995

(7) Principal Investigator:
Kent Karstetter, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
Shawn Granger, CPT, MC

(11) Key Words:
swelling
hand & foot surgery
ankle sprains

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Aug b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether pulsing electromagnetic fields after hand and foot surgery will significantly: (a) decrease the initial amount of swelling, (b) decrease the amount of time the area remains swollen, (c) decrease the intensity of pain and time in pain, (d) increase the rate of return of normal motion, (e) decrease the amount of therapy required for rate of healing of skin and fracture, (f) decrease the amount of therapy required for return of normal motion.

(16) Technical Approach: 400 patients will be randomly assigned to one of two groups. Group I will use the stimulator, but it will not be turned on (control). Group II will use the stimulator and it will be turned on. Swelling will be assessed.

(17) Progress: Study just approved and begun, funding has been approved. Study will start in October 1994. FY95: Investigators PCS'd.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 93/227 (3) Status: Ongoing

(4) Title: Comparison of Modulus Compatible Stability (MCS) Porous Coated Hip System Either with or without Hydroxylapatite (HA) Mineral Coating, Placed without Bone Cement; and the MCS Socket Portion, with or without HA Coating, Placed without Bone Cement along with a Cemented Femoral Stem to Stem to Hip Prostheses Placed with Bone Cement

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho. (10) Associate Investigators
Bradley Nelson, CPT, MC

(11) Key Words:
total hip replacement
press fit
cement

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 32
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and effectiveness of the MCS total hip system.

(16) Technical Approach: 50 patients will be enrolled from FAMC. 1200 patients will be enrolled nationwide. P.I. will decide whether patients require a cemented or uncemented prosthesis. If P.I. does not use cement, patients will be randomly assigned to receive either a porous coated prosthesis or a porous coated prosthesis with an HA coating.

(17) Progress: Just received committee approval. Will begin very soon.

FY94: To date 24 patients with 27 total hip replacements enrolled.

FY95: Five additional patients enrolled.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 95 (2) Protocol #: 93/229A (3) Status: Completed

(4) Title: Evaluation of the Repeat Harvest of the Central One-Third of the Patellar Tendon in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date: Dec 94

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Orthopedics (10) Associate Investigators
Bruce E. Piatt, MD

(11) Key Words: Wayne K. Gersoff, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 19
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study will evaluate (a) the ultimate strength of a repeat harvest of central one-third patellar tendons. (2) the strength of a repeat harvest of central one-third patellar tendons which were left open on initial harvest, compared to that of central one-third patellar tendons which were closed on initial harvest.

(16) Technical Approach: In group I, 10 goats will have the central 1/3 removed from their knees; after removal, the tendons will be left open. In the contralateral control knees, the patellar tendon will be incised, but no material will be excised. In Group II, 10 goats will have the central 1/3 removed from their right knees; after removal the tendons will be closed. In the contralateral knees, the patellar tendon will be incised, but no material will be excised. All goats will undergo euthanasia 6 months after surgery. The tendons will be harvested for biomechanical analysis.

(17) Progress: 19 animals were used this FY. FY95: Study completed and submitted for presentation and publication.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-200

The Anatomic and Functional Evaluation of Mastectomy Patients by Lymphoscintigraphy: Postoperative Changes and Implications for Therapy

START DATE: Dec 93 EST COMP DATE: Apr 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Sharon Hammond, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen

ASSOCIATE INVESTIGATORS: Sun Kim, MAJ, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: mastectomy, lymphoscintigraphy

OBJECTIVE: To accurately describe and quantify the changes in the lymphatic system of the upper extremity following axillary node dissection with either mastectomy or lumpectomy, and to explore the association, if any, between these changes and the development of clinically impaired lymphatic drainage, also to develop a background for the future evaluation of the effectiveness of various postoperative interventions in the prevention of clinical lymphatic obstruction.

TECHNICAL APPROACH: Three nuclear medicine physicians will be blinded as to pre- and post, and objective signs, such as collateral vessels, will be used to grade the study. The grading will be done separately, and raters will not know one another's scores.

PROGRESS:

Number of subjects enrolled to date: 8

Number of subjects enrolled for reporting period: 6

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Six of the eight subjects enrolled have completed the study. Although complete blinded analysis has not yet been formally completed, it appears that two of the six subjects have demonstrated increased lymphatic flow and uptake, which is actually contrary to what would be seen if the original hypothesis was correct; namely a surgical disruption of the lymphatic drainage pathways. The third subject showed decreased lymphatic flow. Two patients have shown evidence for possible venous flow changes. Further evaluation and analysis is currently underway.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-202

A Randomized, Open-Label, Parallel Group Comparison of the Safety and Efficacy of Lovenox (Enoxaparin) Injection vs Coumadin (Adjusted Dose Warfarin) in the Prevention of Thromboembolic Disease Following Hip Replacement Surgery, IND#31532

START DATE: Feb 94 EST COMP DATE: Feb 96 STATUS: Completed

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Bradley Nelson, CPT, MC

PERIODIC REVIEW DATE: 3 Jan 95 REVIEW RESULTS: Completed

FUNDING: Biomedical Research Foundation of Colorado

GIFTS: NA

KEY WORDS: Lovenox, Coumadin, blood clot

OBJECTIVE: To compare the effectiveness of enoxaparin and warfarin to prevent blood clots following hip replacement surgery.

TECHNICAL APPROACH: Randomized clinical trial of 4,500 patients at 150 medical centers in the US. Thirty patients are expected to be studied at FAMC. Followup exams will occur at 6 and 12 weeks postop.

PROGRESS:

Number of subjects enrolled to date: 15

Number of subjects enrolled for reporting period: 4

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): 2 Jun 94, pt 003, hypoxemia; 19 Sep 94, pt 10, shortness of breath

Summary of prior and current progress: Currently on schedule to finish 30 patient enrollment by Jan 95.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-203

An Evaluation of the Lymphatic System in Breast Cancer Patients Undergoing Axillary Lymph Node Dissections: Lymphatic Changes and Implications for Therapy

START DATE: Mar 94 EST COMP DATE: Mar 98 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Sharon Hammond, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen Surg

ASSOCIATE INVESTIGATORS: Mike McBiles, LTC, MC, Chet Morrison, CPT, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: breast cancer, node dissection, lymphatic changes

OBJECTIVE: To get a clearer picture of the changes to the lymphatic system after lumpectomy or mastectomy.

TECHNICAL APPROACH: Using lymphoscintigraphy (LSC), patients undergoing axillary lymph node dissections for breast CA will be studied, focusing on both anatomic changes as well as functional alteration. In part one, pre-op and post op and 6 week LSC evaluation will be obtained, along with upper extremity circumference measurements, and venous duplex somography exams. The latter will document the degree of swelling, and ascertain that the swelling is not from venous obstruction. Patients will be followed for complications of extremity infection and its association with lymphedema. In part two, patients with abnormal LSC at 6 weeks will be randomized to either observation or early lymphatic compression, with compression therapy continuing for one month. Lymphatic function will be reassessed one month following randomization.

PROGRESS:

Number of subjects enrolled to date: 4

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Enrollment continuing.

FY95: No progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-204

Effect of Pre-Surgical Pain Control Training on Recovery

START DATE: Jan 94 EST COMP DATE: Dec 95 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Janet Wilson, MAJ, AN

FACILITY/DEPT/SVC: FAMC/Surg/Orth Surg

ASSOCIATE INVESTIGATORS: LTC Susan Reznick, MAJ Howard Place,
MAJ Lorette Chang, MAJ Charles Hathaway, Richard Sherman, LTC,
MS,

PERIODIC REVIEW DATE: 30 Sep 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: relaxation training

OBJECTIVE: To determine whether teaching people (a) to control their pain and stress through relaxation/biofeedback training and (b) about what will happen during their surgery and recovery period (including drains, common vocabulary, likely sensations, time for each stage of recovery, etc.) will significantly reduce (a) need for pain medications, (b) time in the hospital, (c) complications, (d) amount of nursing contact required as well as results in positive changes in other major outcome measures.

TECHNICAL APPROACH: As per objective.

PROGRESS:

Number of subjects enrolled to date: 13

Number of subjects enrolled for reporting period: 2

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Ten control patients have completed the study. Need ten experimental subjects.

FY95: Two new subjects enrolled during FY95 for a total of 13.

All investigators PCS'd, no final report.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-205

Diagnostic and Prognostic Application of Blood Cholesterol and Lactate Measurements in Patients with Undiagnosed Intra-Abdominal Processes

START DATE: Feb 94 EST COMP DATE: Jul 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: David Greco, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen Surg

ASSOCIATE INVESTIGATORS: Anne Flynn, MAJ, MC

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: lab measurements, abdominal pain

OBJECTIVE: To identify any correlation between blood cholesterol, lactate and the diagnosis of abdominal diseases.

TECHNICAL APPROACH: Laboratory study of blood specimens as per title.

PROGRESS:

Number of subjects enrolled to date: 15

Number of subjects enrolled for reporting period: 10

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Difficulty encouraging on-call residents to enroll patients in the protocol. Will continue to educate on-call residents.

FY95: To date a total of 15 subjects are enrolled. Ten new subjects enrolled since the start of FY95.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-206A

Porous Polyethylene (Medpor) as a Corneal Intrastromal Support for a Keratoprosthesis in the Stauffland Rabbit (Oryctolagus cuniculus)

START DATE: Feb 94 EST COMP DATE: Aug 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Eric Sieck, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophthalm

ASSOCIATE INVESTIGATORS: Robert Enzenauer, LTC, MC, John Miller, Matthew Uyemura, CPT, MC

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: MedPor implants

KEY WORDS: keratoprosthesis

OBJECTIVE: To determine the feasibility of a porous polyethylene intracorneal implant for long-term support of a polymethylmethacrylate (PMMA) keratoprosthesis in a rabbit model. In addition, to quantify the histologic vascular and fibrous ingrowth into the prosthetic material.

TECHNICAL APPROACH: Ten female Stauffland rabbits will be used as experimental subjects with surgical procedures as described in the protocol. Clinical parameters of tissue acceptance, complications, and healing will be observed and recorded. Special attention will be paid to any atrophy, melting, infection, or leaking. Histological examination of the tissue will also be performed.

PROGRESS:

Number of subjects enrolled to date: 10

Number of subjects enrolled for reporting period: 10

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Porous polyethylene stromal supports have been implanted in ten rabbits and two keratoprostheses have been placed. Four rabbits have been euthanized and the studied eyes enucleated.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-208A

Development of an Infection Resistant External Fixator System and a Tibially Implanted, Percutaneous Limb Prosthetic Holder

START DATE: Feb 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Wayne A. Johnson, CPT, MC

PERIODIC REVIEW DATE: Jan 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: prosthetic, fixator, implant

OBJECTIVE: Overall to develop a prosthetic attachment system for amputees which can be directly implanted into the major weight bearing bone and be extended through the skin and to develop an external fixator coating which will resist Infection for at least one year.

TECHNICAL APPROACH: Phase III - Test of infection barrier and skin ingrowth using hydroxylapatite coated and uncoated titanium screws implanted percutaneously into goats' bones. Ten goats, half with 4 untreated screws and half with 4 treated screws implanted will be evaluated for an 8-month period.

PROGRESS:

Number of subjects enrolled to date: 4

Number of subjects enrolled for reporting period: 2

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Surgeries have begun. Animals are being observed, but it is too early to draw conclusions. FY95: All animals doing extremely well and have started full study.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-209A

Examination of the Effect of Transforming Growth Factor Alpha (TGF α) and Retinoic Acid on Ototoxic Damaged Guinea Pig Neuroepithelium: A Pilot Study

START DATE: Mar 94 EST COMP DATE: Jun 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Richard Kopke, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Otolar

ASSOCIATE INVESTIGATORS: Ronald Jackson, Ph.D., David Asher, Ph.D., Matthew Schofield, CPT, MS, Yehoash Raphael, Ph.D., U of Mich.

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: neuroepithelium

OBJECTIVE: To determine whether infused perilymphatic transforming growth factor alpha and retinoic acid in combination will induce hair cell regeneration in guinea pig cochleas damaged by kanamycin.

TECHNICAL APPROACH: Nine animals divided into three groups: a control group (C1) and two experimental groups; Experimental 1 - Kanamycin Group (E1) and Experimental 2 (Kanamycin + growth factor group). Mini osmotic pumps will be implanted and infusion administered per experimental design.

PROGRESS:

Number of subjects enrolled to date: 9

Number of subjects enrolled for reporting period: 9

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Nine animals were implanted with miniosmotic pumps; all were given Kanamycin; 6 animals received growth factors. Only one animal should mitotically active cells in damaged cochlea (determined by anti-BrdU analysis. Principal investigator left Jun 94. Will be replaced by Dr. Yoshida.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-210

Efficiency of Three Hearing Instrument Selection Procedures

START DATE: May 94 EST COMP DATE: Jun 95 STATUS: Withdrawn

PRINCIPAL INVESTIGATOR: Dennis Williams, LTC, MS

FACILITY/DEPT/SVC: FAMC/Surg/Audiology

ASSOCIATE INVESTIGATORS: Matthew Brandow, 1LT, MS

PERIODIC REVIEW DATE: Apr 95 REVIEW RESULTS: Withdrawn

FUNDING: NA

GIFTS: NA

KEY WORDS: hearing aids

OBJECTIVE: To determine the clinical accuracy of three hearing instrument selection procedures.

TECHNICAL APPROACH: Retiree at-cost hearing aid program subjects divided three groups, 50 subjects each: Audiogram Procedure, Real Ear Unaided Response (REUR) Procedure, and REUR/Real Ear Coupler Difference (RECD) Procedure.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress. Study not started.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-211

Use of Pulsing Electromagnetic Fields for the Treatment of Limb Pain

START DATE: May 94 EST COMP DATE: May 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Kent Karstetter, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Jeffrey Hrutkay, MAJ, MC, Bendt Peterson, CPT, MC, FAMC; Richard Sherman, LTC, MS, D.E. Casey Jones, LTC, MC, Madigan AMC; Jeffrey Ginther, LTC, MC, Evans ACH; Steve Pals, MAJ, MC, Scott Schaffer, 1LT, MPT, Reynolds ACH

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Terminated

FUNDING: MRDC ?

GIFTS: Loan of equipment

KEY WORDS: pain control, electromagnetic fields

OBJECTIVE: The overall objectives of the program are to determine whether pulsing electromagnetic fields, (PEMFs) can reduce swelling after hand, ACL, and foot surgery of simple fractures of the long bones faster and further than standard techniques and reduce the recovery time after stress fractures and ACL related knee pain.

TECHNICAL APPROACH: Swelling of the involved limb will be measured either by submersion in water, by pressure sensor called a "cast alert" or algometer. Photographs will be taken of the surgical site. Subjects will participate for 1 1/2 hours per day for a maximum of 2 weeks. The limb will be inserted in the PEMF for one hours and measurements for 15 minutes.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The PI did not submit a report in a 2-year period.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-212

Comparison of Stiffness in Distal Radius Fractures After
Injection of Steroid, Injection of Lidocaine, or No Injection at
Time of Immobilization

START DATE: Jun 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Jeffrey Hrutkay, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: David Kim, CPT, MC, William Pace, CPT,
MC, D.E. Casey Jones, LTC, MC (Madigan AMC)

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: fracture, inflammation, steroid, lidocaine

OBJECTIVE: To compare the stiffness which occurs during healing
of distal radius fractures after injection of steroid, injection
of lidocaine, or no injection at time of immobilization.

TECHNICAL APPROACH: Ten patients will be initially assigned to
each of three groups. All patients will undergo hand/wrist
evaluation at discontinuance of immobilization, at 8 wks, at 12
wks, and at 6 months following fracture. Wrist motion, digital
motion, grip strength, and pinch strength will be evaluated and
compared with the unfractured contralateral limb as a control.
The percent differences will be compared between groups to
determine if they show statistical significance.

PROGRESS:

Number of subjects enrolled to date: 15

Number of subjects enrolled for reporting period: 15

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None.

Summary of prior and current progress: Waiting for possible
funding from Women's Research Initiative or from VA/DOD
application.

FY95: Fifteen subjects enrolled to date. Anticipate completion
of study by June 1996.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-213A

Repair of Rat Femoral Artery and Rabbit Auricular Artery by
Microvascular Technique

START DATE: May 94 EST COMP DATE: Jun 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Steven Topper, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: May 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: surgical training, microvascular technique

OBJECTIVE: Ongoing training of Hand Surgery Service to maintain
proficiency in the microsurgical repair of small vessels, nerves
and tendons.

TECHNICAL APPROACH: Arteries of 0.7 mm to 1.2 mm in diameter
will undergo transection, followed by microvascular surgical
anastomosis.

PROGRESS:

Number of subjects enrolled to date: 7

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: Protocol is ongoing.

FY95: Terminated due to termination of GME program.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-214A

Effects of Increased Levels of Glutathione on Traumatic Cataracts
in Albino Rats (Rattus Norvegicus)

START DATE: 1 Aug 94 EST COMP DATE: Oct 94 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Larry Andreo, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Monte Dirks, LTC, MC

PERIODIC REVIEW DATE: Jul 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: cataracts, glutathione

OBJECTIVE: To determine the effects of increased glutathione levels on the density and resolution of traumatic cataracts in white rats.

TECHNICAL APPROACH: Pilot study using 5 rats in the treatment group and 5 as controls, followed one month later using the remaining 18 rats.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Not started. FY95: PI PCS'd.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-215A

Effects of 5-Fluorouracil on Adhesion Characteristics in Strabismus Surgery in the Stauffland Rabbit (Oryctolagus cuniculus)

START DATE: Sep 94 EST COMP DATE: 1 Oct 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Larry Andreo, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Monte Dirks, LTC, MC

PERIODIC REVIEW DATE: Jul 95 REVIEW RESULTS: Completed

FUNDING: NA

GIFTS: NA

KEY WORDS: strabismus, adhesion, 5-fluorouracil

OBJECTIVE: To assess the impact of anti-fibroblastic agents such as 5-FU on the strength and extent of scarring of extraocular muscles and conjunctiva in strabismus eye surgery.

TECHNICAL APPROACH: One half of the attachments will be treated with 5-FU and will be compared for strength of attachment and scarring the attachments not treated with 5-FU.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Not started. FY95: Study completed and presented at Association for Research in Vision and Ophthalmology, May 17, 1995.

PUBLICATIONS: None.

PRESENTATIONS: As above.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-216

A One-Year, Parallel, Randomized, Double-Masked, Active-Controlled, Multiclinic Study Comparing the Corneal Safety of 2% MK-507 Ophthalmic Solution, 0.5% Timolol Ophthalmic Solution, and 0.5% Betaxolol Ophthalmic Solution in Patients with Elevated Intraocular Pressure with Ocular Hypertension or Glaucoma.
(IND#46,041-MK 0507, 048-01)

START DATE: 3/15/95 EST COMP DATE: Apr 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Monte Dirks, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophthal

ASSOCIATE INVESTIGATORS: Robert Dragoo, COL, MC, Eric Sieck, MAJ, MC, David Zumbro, CPT, MC, Jeffrey Heier, CPT, MC, Matthew Uyemura, CPT, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Pending
FUNDING: \$26,000 grant from Merck deposited in Biomed.
GIFTS:

KEY WORDS: glaucoma

OBJECTIVE: Compare: 1) change in cell counts; 2) change in corneal thickness; 3) safety profiles after treatment with MK507, Timolol, and Betaxolol.

TECHNICAL APPROACH: Randomized, parallel, double masked, active controlled for 1 year of monotherapy.

PROGRESS:

Number of subjects enrolled to date: 28
Number of subjects enrolled for reporting period: 28
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None at FAMC.

Summary of prior and current progress: Currently all 28 patients who enrolled in the study are at or currently at or approaching the 180 day mark. All patients are doing well in the study without any significant AE's.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-217A

Evaluation of Bilateral Oophorectomy with and without a High Phosphorous Diet for the Induction of Osteoporosis in Mature Female Goats

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Vincent Battista, CPT, MC

PERIODIC REVIEW DATE: Aug 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: osteoporosis, oophorectomy, diet

OBJECTIVE: (1) To provide a comparison of bone tissue from steroid-induced osteoporosis vs oophorectomy-induced osteoporosis. (2) To determine whether the use of steroids vs the use of oophorectomy would be the most rapid way to induce osteoporosis. (Data from this study to be compared to concurrent steroid protocol.)

TECHNICAL APPROACH: Four goats will undergo bilateral oophorectomy. Two will receive a high phosphorous diet and two will receive a standard diet. The presence of osteoporosis will be determined through a transiliac crest biopsy and a Lunar DPXL bone scan to be performed at baseline, 2 weeks after oophorectomy, and monthly thereafter.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Not started yet.

FY95: Terminated due to lack of progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-218A

Refinement of the Surgical Technique for the Implantation of Two types of Lumbar Vertebral Prostheses in a Goat Model (Capra hircus)

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Howard Place, MAJ, MC, Mark Clyde, CPT, MC, Vincent Battista, CPT, MC

PERIODIC REVIEW DATE: Aug 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: surgical technique

OBJECTIVE: (1) To refine the surgical technique for the implantation of experimental lumbar prostheses. (2) To refine the techniques for histological and biomechanical analyses of the implants.

TECHNICAL APPROACH: Four goats will receive a lumbar vertebral prosthesis. In Group I, two goats will receive an implant which will replace a disk at the L4-L5 junction. In Group II, two animals will receive an implant which will be inserted through the axial plane of the vertebral body of the L4 vertebra. Euthanasia will occur 6 weeks after implantation. The implants will undergo histological and biomechanical testing.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Study just approved.
FY95: Terminated due to lack of progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-219A

Determination of the Optimum Dosing of Solu-Medrol
(Methylprednisolone Sodium Succinate) Required to Induce
Osteoporosis in Mature Female Goats

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Vincent Battista, CPT, MC

PERIODIC REVIEW DATE: Aug 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: osteoporosis

OBJECTIVE: (1) To determine the dosage of Solu-Medrol which is required to induce osteoporosis in the goat. (2) To provide a comparison of bone tissue from steroid-induced osteoporosis vs oophorectomy-induced osteoporosis. (3) To determine whether the use of steroids vs the use of oophorectomy would be the most rapid way to induce osteoporosis in the goat. (data from this study will be compared to concurrent oophorectomy protocol.)

TECHNICAL APPROACH: Four goats will receive 60 mg/day of Solu-Medrol and two will receive 120 mg/day. The presence of osteoporosis will be determined through a transiliac crest biopsy and a Lunard DPXL bone scan to be performed at baseline, 2 weeks after oophorectomy, and monthly thereafter.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No progress yet. Study just approved. FY95: Terminated due to lack of progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-200

Evaluation of the Performance Impact and Treatment of Exercise Induced Urinary Incontinence among Female Soldiers

START DATE: Sep 95 EST COMP DATE: ? STATUS: Terminated

PRINCIPAL INVESTIGATOR: Gary Davis, COL, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ob-Gyn

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: PI PCS'd before starting the study.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-201

95-201 One-time Use of IND, Brolene, for Acanthamoeba Keratitis
in Patient MC

START DATE: Oct 94 EST COMP DATE: Oct 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: David S. Zumbro, CPT, MC, and Eric A.
Sieck, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: IND, Brolene, Acanthamoeba Keratitis

OBJECTIVE: IND treatment due to failure of standard treatments.

TECHNICAL APPROACH: Medicine was used every hour around the
clock initially and then tapered to the current regimen of 4
times a day.

PROGRESS:

Number of subjects enrolled to date: 1

Number of subjects enrolled for reporting period: 1

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None

Summary of prior and current progress: No recurrence of the
Acanthamoeba keratitis.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-202

Dilute Pilocarpine Stimulation of Tear Production in Patients
with Sjogren's Syndrome

START DATE: EST COMP DATE: STATUS: Terminated

PRINCIPAL INVESTIGATOR: Matthew Uyemura, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

 Number of subjects enrolled to date:

 Number of subjects enrolled for reporting period:

 Nature and Extent of Significant Adverse Events (reported to
 the FDA or sponsor):

Summary of prior and current progress: PI withdrew/terminated
study due to difficulties in complying with IRC's stipulations
for approval.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-203

The Non-Invasive Detection and Characterization, Treatment and Potential Prevention of Anal Incontinence in the Parous Female Population

START DATE: Feb 95 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Anthony LaPorta, COL, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen Surg

ASSOCIATE INVESTIGATORS: Bradley Bute, LTC, MC, Clinton Beverly, CPT, MC, Phillip Mallory, LTC, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: DWHRP

GIFTS: \$148,500

KEY WORDS: anal incontinence, pregnancy

OBJECTIVE: To determine whether bowel incontinence after pregnancy is due to muscle problems, nerve injury or a combination of both.

TECHNICAL APPROACH: During the 6th month of pregnancy and three months after delivery, subjects will have ultrasound of the anal sphincter muscles to map out the muscles of continence to determine if there are any weaknesses or problems present. Nerve stimulation and manometry will also be performed in 300 subjects.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Subjects are being enrolled at Evans ACH, with Madigan AMC later approved as an additional site. There was change of PI at FAMC due to PCS. All required equipment has been received and made operational. The investigative team has been uptrained on all modalities of this research. Actual data accrual will begin in the latter part of Aug 95.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-204A

Porous Polyethylene (Medpor) as a Corneal Intrastromal Support
for a Keratoprosthesis in the Stauffland Rabbit

START DATE: 19 Jun 95 EST COMP DATE: 19 Mar 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Eric Sieck, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Matthew Uyemura, CPT, MC, John Miller,
CPT, MC

PERIODIC REVIEW DATE: 2 Aug 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: keratoprosthesis

OBJECTIVE: Use of Medpor implant for support of
keratoprosthesis.

TECHNICAL APPROACH: Intrastromal lamellar inlay of porous
polyethylene disc. Second procedure is placement of
keratoprosthesis.

PROGRESS:

Number of subjects enrolled to date: 10

Number of subjects enrolled for reporting period: 10

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: Discs placed on
19 Jun 95. Keratoprosthesis to be placed when available.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-205A

Introduction to Advanced Laparoscopic Surgical Techniques Using Swine (Sus scrofa).

START DATE: Nov 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Deborah Chan, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ob-Gyn

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: 2 Nov 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: surgical techniques, laparoscopy

OBJECTIVE: To improve skills and apply advanced laparoscopic techniques.

TECHNICAL APPROACH: Use animal model to accomplish objective.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Four physicians trained, 8 hour sessions.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-206A

Evaluation of the Biomechanical Properties of Radii Removed from Sheep which Have Undergone Ovariectomy with and without Estradiol Implants

START DATE: Dec 94 EST COMP DATE: Oct 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Shawn Granger, CPT, MC

FACILITY/DEPT/SVC: FAMC/Orth

ASSOCIATE INVESTIGATORS: Jon Garramone, CPT, MC

PERIODIC REVIEW DATE: 20 Sep 95 REVIEW RESULTS: completed

FUNDING: NA

GIFTS: NA

KEY WORDS: osteoporosis

OBJECTIVE: To evaluate the biomechanical strength of radii taken from sheep which received one of four different treatments. To establish the sheep as a model for osteoporosis research.

TECHNICAL APPROACH: All radii radiographed. All radii scanned for bone mineral density. All radii sectioned. All radii ground and tested biomechanically.

PROGRESS:

Number of subjects enrolled to date: 48

Number of subjects enrolled for reporting period: 48

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The biomechanical testing of these bones was completed by 1 Feb 95 for the four point bending test. Statistical analysis revealed no significant change in four point bending. Also, it was revealed that the bones were one year post ovariectomy, so biomechanical changes would not be anticipated at such an early interval. The nuclear medicine densitometry scans were thus aborted as CSU had hologic QDP-1000 scans available for these bones. No further cross correlation was made.

PUBLICATIONS and PRESENTATIONS: A paper was presented at the Barnard Competition in Denver, and a poster exhibit was presented at the Academy of Surgical Research on 6 Oct 95. The paper is being prepared for publication in the Journal of Clinical Investigation.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-207

A Double-Blind Comparison of the Efficacy and Safety of Extended Outpatient Treatment with Subcutaneous Normiflo Versus Placebo for the Prevention of Venous Thromboembolism in Patients with Hip or Knee Replacement Surgery, and Amendment 1. IND#30,639

START DATE: Mar 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: David Kim, CPT, MC, Shawn Granger, CPT, MC, Steve Friedel, CPT, MC, Mark Clyde, CPT, MC, Bradley Nelson, CPT, MC

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Approved
FUNDING:

GIFTS: Wyeth-Ayerst provides IND drug.

KEY WORDS: Normiflo, thromboembolism, orthopedic surgery

OBJECTIVE: To evaluate the safety and effectiveness of an experimental blood thinner, Normiflo, for the prevention of blood clots following hip or knee replacement surgery.

TECHNICAL APPROACH: During the inpatient phase subjects will receive Normiflo injections twice a day for a least 4 days to a maximum of 10 days. After discharge from the hospital subjects will be randomized to receive Normiflo or placebo. The study drug will be administered under the skin once a day until 6 weeks after surgery. Evaluations will be made at 2 to 3 weeks after surgery and 6 weeks after surgery. Phone contact or a visit to the doctor will be made at 10-12 weeks.

PROGRESS:

Number of subjects enrolled to date: 31

Number of subjects enrolled for reporting period: 31

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): Two adverse events: #009 and #008, pulmonary embolism, possibly drug related

Summary of prior and current progress: Two subjects were discontinued due to a second surgery, one discontinued due to excessive bleeding, one subject was discontinued because another service took over the patient's care and discontinued study drug. Two subjects were unwilling to do the home injections and therefore did not complete the study. Otherwise the study is progressing successfully.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-208

Repair of Displaced Bony Gamekeeper's Thumb Using LUHR Screws
versus Introsseous Wiring

START DATE: EST COMP DATE: STATUS: Terminated

PRINCIPAL INVESTIGATOR:

FACILITY/DEPT/SVC: FAMC/

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

 Number of subjects enrolled to date:

 Number of subjects enrolled for reporting period:

 Nature and Extent of Significant Adverse Events (reported to
 the FDA or sponsor):

Summary of prior and current progress: PI decided to terminate
(not start) study due to announcement of GME closure at FAMC.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-209

Use of the Forte Distal Radius Plate in Unstable Distal Radius Fractures

START DATE: EST COMP DATE: STATUS: Terminated

PRINCIPAL INVESTIGATOR: Steven Topper, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

 Number of subjects enrolled to date:

 Number of subjects enrolled for reporting period:

 Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Due to announcement of closure of GME at FAMC, PI decided not to start the study.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-210

Evaluation of the Accuracy of a Military Database in Terms of Diagnostic, Procedural, and Complication Coding

START DATE: Jan 95 EST COMP DATE: Mar 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Howard Place, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: William Pace, CPT, MC, Lori Harrington, CPT, MC

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: database, medical records

OBJECTIVE: Electronic medical databases are frequently used as a research tool because they provide easy access to a large amount of information and are easy to manipulate. However, previous studies have questioned the value of the information contained in such databases. This study was performed to determine the accuracy of routine hospital-assigned ICD-9-CM database codings (International Classification of Disease, Version 9, Clinical Modification).

TECHNICAL APPROACH: Two independent physicians reviewed the charts of 99 consecutive total joint surgery patients for diagnoses, procedures performed, and complications. Hospital-assigned database codings were compared with the independent reviews and were analyzed for statistically significant differences.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Thirty-nine percent of the database records were missing two or more diagnoses. Twenty-seven percent were missing two or more of the procedures performed. Twenty-eight percent were missing one or more complications.

PUBLICATIONS: None.

PRESENTATIONS: 37th Annual SOMOS Meeting, 3-8 Dec 95, Vail, CO

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-211

Comparison of Three-Portal Knee Arthroscopy Versus Two-Portal
Quadriciceps-Sparing Arthroscopy with Evaluation of Early
Functional Recovery

START DATE: Feb 95 EST COMP DATE: Aug 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: John Reister, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: John McBride, LT, MC, Roy Osborn, MAJ,
SP

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: arthroscopy

OBJECTIVE: To compare the functional rehabilitation results
which follow two portal versus three-portal knee arthroscopy.

TECHNICAL APPROACH: Prospective study in which 40 patients will
be randomly assigned to two-portal knee arthroscopy or to three-
portal arthroscopy.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): ?

Summary of prior and current progress: Investigators failed to
provide a progress report for the fiscal year.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-212

NM 23 "Antimetastatic" Gene Product Expression in Head and Neck Squamous Cell Carcinoma

START DATE: Feb 95 EST COMP DATE: Jun 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Angie Song, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/ENT

ASSOCIATE INVESTIGATORS: Glen Yoshida, LTC, MC, Stephen Groo, MAJ, MC

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: carcinoma

OBJECTIVE: To determine the validity for using NM23 expression value as a means of predicting nodal status, distant metastasis, and overall survival.

TECHNICAL APPROACH: Laboratory analysis of patients' specimens.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: The investigators failed to provide a report for the fiscal year.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-213

Simulated Media Opacities Causing Transient Apparent Afferent
Pupillary Defects Using Neutral Density Filters

START DATE: Feb 95 EST COMP DATE: May 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Matthew Uyemura, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Michael Frye, SPC, USA, Kimberley
Peele, MAJ, MC

PERIODIC REVIEW DATE: 5 Apr 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: afferent pupillary defect, neutral density filters

OBJECTIVE: To determine the length of time of an apparent
afferent pupillary defect caused by a media opacity.

TECHNICAL APPROACH: By placing a neutral density filter over one
eye, we were able to measure the amount of time that an apparent
afferent pupillary defect persisted in that eye.

PROGRESS:

Number of subjects enrolled to date: 11

Number of subjects enrolled for reporting period: 11

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None.

Summary of prior and current progress: In the 4 subjects less
than 31yo, the average duration of the AAPD was 66.3 minutes
(standard deviation 7.5, range 60-75 minutes), while the average
duration of the 7 subjects aged 54-74 was 88.6 min (SD 13.8,
range 75-105 min) which was statistically significant ($p < 0.02$,
one-way analysis of variance). There was no significant
difference in duration when comparing sex or eye color.

PUBLICATIONS: None.

PRESENTATIONS: Post presentation at the ARVO annual meeting in
Ft. Lauderdale, FL, May 1995.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-214A

Isolation and Culture of Cartilage Chondrocytes from Hooves of Sheep (Ovis aries) and Goats (Capra hircus).

START DATE: EST COMP DATE: STATUS: Completed

PRINCIPAL INVESTIGATOR: Shawn Granger, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Jun 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: chondrocytes

OBJECTIVE: To perfect the techniques of isolation and culture of chondrocytes in a collagen matrix.

TECHNICAL APPROACH: Both fetal and adult ovine articular cartilage were prepared for culture by dissection and proteolytic digestion under sterile techniques. Cells were seeded at high density in vessels that were coated and non-coated. Coated culture flasks were layered with a commercially prepared rat tail collagen matrix (collagen II, Sigma Co.)

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Growth patterns were noted to be different under the two separate treatments. Initial cell growth was greater in coated flasks compared to non-coated ones. After 5 days growth, however, either treatment condition was not different. As expected, fetally derived cells produced the best growth results. Cell morphology was confirmed with phase contrast photomicrography. Cells were removed by trypsin digestion, frozen in liquid nitrogen and later rethawed and revitalized. Therefore, we have validated that our lab can isolate, establish, maintain and characterize cultures of chondrocytes.

PUBLICATIONS and PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-215

Comparison of the Stability of Bipolar versus Unipolar
Hemiarthroplasty in an In vitro Model

START DATE: Mar 95 EST COMP DATE: Jun 95 STATUS: Completed.

PRINCIPAL INVESTIGATOR: John Reister, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: David Kim, MAJ, MC, Edward Lisecki,
LTC, MC

PERIODIC REVIEW DATE: Feb 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: hemiarthroplasty

OBJECTIVE: To measure the in vitro stability of unipolar versus
bipolar prostheses.

TECHNICAL APPROACH: Two cadaveric hemipelvises with intact
labrum were harvested. A metal jig was constructed to hold the
hemipelvises stable and allow articulation of a femur-prosthetic
component. The jig allowed free positioning of the hemipelvises,
as well as adjustments of the center of rotation, adduction, and
internal rotation. Each trial consisted of 10 repetitions per
endoprosthetic head. The flexion arc that produced dislocation
was the measured endpoint of each repetition.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: Many of the dynamic
forces created by muscle action were not reproduced with this
model. However, such conditions applied equally to both designs
tested. The unipolar prosthesis is more stable than an equal
neck length bipolar prosthesis. If a bipolar prosthesis is
selected, use as long a neck length as possible to increase
stability in provocative positions.

PUBLICATIONS:

PRESENTATIONS: 37th Annual SOMOS Meeting, 3-8 Dec 95, Vail, CO

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-216

Accuracy of Pedicle Screw Placement as Assessed by Computed Tomography versus Anatomic Dissection in Cadaver Spines

START DATE: Mar 95 EST COMP DATE: Apr 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Gerald Farber, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Howard Place, LTC, MC, Thomas Damiano, MAJ, MC, Michael Grant, MAJ, MC

PERIODIC REVIEW DATE: 6 Feb 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: computed tomography, pedicle screw

OBJECTIVE: The presence of artifact on some CT images led to the performance of this study to assess the validity of CT for evaluating postoperative pedicle screw placement.

TECHNICAL APPROACH: Two cadaver spines were instrumented bilaterally with 24 pedicle screws from L2-S1. Each spine was then imaged with CT. The CT studies were evaluated by an orthopedic surgeon and a radiologist, who worked independently of each other. Each screw was evaluated for accuracy of placement and direction of misplacement, if appropriate (superior, inferior, medial, or lateral). The spines were dissected by two orthopedic surgeons to determine the placement of each pedicle screw and the direction of misplacement, if any. The findings from the anatomic dissection were considered to be the true placement of pedicle screws.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: CT can be used to accurately assess corical penetration in the placement of pedicle screws. A high degree of suspicion should be maintained while evaluating CT scans, and any question of pedicle cortical violation most likely represents an actual penetration.

PUBLICATIONS: None reported.

PRESENTATIONS: 37th Annual SOMOS meeting, 3-8 Dec 95, Vail, CO.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-217

A Biomechanical Comparison of Two Fixation Methods of First Metatarsophalangeal Joint Arthrodesis: A Cadaveric Study

START DATE: Feb 95 EST COMP DATE: Aug 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: David Kim, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Jeffrey Hrutkay, LTC, MC

PERIODIC REVIEW DATE: 7 Mar 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS:

OBJECTIVE: To determine if the spherical fusion with miniplate is biomechanically superior to the dorsal AO plate with flat osteotomy.

TECHNICAL APPROACH: Five pairs of cadaveric lower extremities will be radiographed before implant fixation. For each matched pair, each leg will be randomly assigned to undergo first metatarsophalangeal joint fusion using one of the two different methods described above. Once the hardware is placed, radiographs will be taken to ensure adequate fixation. Stiffness will be tested using the Instron Materials Testing Device against a dorsiflexion load to simulate weight-bearing situations. The force will be applied to the point of failure.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: Investigators failed to provide a report for the fiscal year.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-218A

Effect of Topical Administration of Timololon Oxygen-Induced Retinopathy in the Newborn Rat

START DATE: Aug 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Matthew Uyemura, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Jeffery Heier, CPT, MC, William Waterhouse, MAJ, MC, Monte Dirks, MAJ, MC

PERIODIC REVIEW DATE: 2 Aug 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: retinopathy of prematurity, timolol

OBJECTIVE: To determine if topical vasoconstrictive agents can decrease the incidence of retinopathy of prematurity in a rat model.

TECHNICAL APPROACH: Timolol (vasoconstrictor) or placebo (normal saline) drops will be placed in the rat pups eyes twice a day while they are being given high concentrations of oxygen. The retinas will be examinaed after 10 days.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Two rats are ready to deliver one litter each.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-219A

Drilling of Porous Polyethylene (Medpor) Orbital Implant for Motility Peg Sleeve in a Goat Model (Capra hircus)

START DATE: 25 Jul 95 EST COMP DATE: Apr 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Matthew Uyemura, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Stuart Farris, Thomas Damiano, MAJ, MC, Glen Sandberg, MAJ, MC

PERIODIC REVIEW DATE: 2 Aug 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: porous polyethylene orbital implant, motility peg sleeve, goat model

OBJECTIVE: To determine if a porous polyethylene orbital implant can be safely and effectively drilled to improve prosthetic mobility.

TECHNICAL APPROACH: Porous polyethylene orbital implants will be placed in six goat orbits and allowed to vascularize. They will then be drilled and later examined.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Porous polyethylene orbital implants have been placed in four goats successfully. The other two implants will be placed 8 Aug 95.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-220A

Modified Jones Tube Using a Porous Polyethylene Sleeve in a Goat Model

START DATE: Aug 95 EST COMP DATE: Nov 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: David Zumbro, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Stuart Farris, MAJ, MC

PERIODIC REVIEW DATE: Feb 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: modified Jones Tube, polyethylene, goat model

OBJECTIVE: To determine if a polyethylene sleeve on a Jones tube decreases extrusion, migration of tube and other associated complications.

TECHNICAL APPROACH: DCR on a goat with placement of modified Jones tube and observation for 6 weeks

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: One goat had surgery in the middle of August and the other five had surgery on 12 Sep.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-221A

Evaluation of Collagen/Vicryl Mesh for Reconstruction of Pharyngeal Wall Defects in Immature Pig (Sus scrofa)

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Glen Yoshida, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Otolaryn

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: 28 Aug 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: Evaluation of collagen/vicryl mesh for the reconstruction of pharyngeal wall defects.

TECHNICAL APPROACH: No change from protocol.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Three pigs have all done with post-op without complications. Reconstructed sites exhibit normal appearing mucosa without stricture. Histological examination is pending.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-222A

Effects of Cyclosporin A on Bleb Fibrosis in Stauffland Rabbit

START DATE: Apr 95 EST COMP DATE: May 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Larry Andreo, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophthal

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Mar 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: glaucoma, fibrosis, cyclosporine A

OBJECTIVE: To assess the effects of an immunosuppressive topically applied on the amount of fibrosis around a glaucoma valve implant.

TECHNICAL APPROACH: Ammed valve glaucoma implants were surgically implanted in Stauffland rabbits. One half were treated with 2% cyclosporine A in olive oil and half treated with olive oil alone. The thickness of the bleb fibrosis was then measured after 45 days of treatment.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Treatment is finished, eyes enucleated, and slides submitted to pathologist.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-223A

Effects of Mitomycin C on Adhesion Characteristics in Stabismus
Surgery in Stauffland Rabbit

START DATE: EST COMP DATE: STATUS: Terminated

PRINCIPAL INVESTIGATOR: Larry Andreo, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophthal

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Mar 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

 Number of subjects enrolled to date:

 Number of subjects enrolled for reporting period:

 Nature and Extent of Significant Adverse Events (reported to
 the FDA or sponsor):

Summary of prior and current progress: This study was cancelled
due to PCS of principal investigator.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-224A

Development of an Infection Resistant External Fixator System and a Percutaneous Limb Prosthetic Holder in a Goat Model

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Lori Harrington, CPT, MC

PERIODIC REVIEW DATE: Jun 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: To evaluate a percutaneous prosthetic attachment system in terms of complications, infection rate, attachment strength, and skin adherence. To evaluate an external fixator system in terms of infection rate and growth of skin to the fixator system.

TECHNICAL APPROACH: Twenty-five goats will be divided into five groups, based on time of euthanasia (3,6,12,26 or 52 weeks). Each goat will receive a prosthetic holder in one hindleg. Within each group of five goats, three goats will receive four HA coated pins and two goats will receive uncoated pins in the lumbar vertebrae. The goats will be followed to determine the number of infections which occur and the amount of skin adherence.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: HA-coated external fixators are being prepared. Hope to begin surgeries soon.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-225A

Effect of Ketolorac on Bone Ingrowth and Attachment Strength in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Bradley Nelson, CPT, MC, Wayne Johnson, CPT, MC

PERIODIC REVIEW DATE: May 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: To quantify the effects of ketorolac on bone ingrowth and attachment strength of hydroxyapatite coated and uncoated implants.

TECHNICAL APPROACH: Fifteen goats will be divided into three groups, based on time of euthanasia (3,6, or 12 weeks). With in each group, three goats will receive ketorolac and two goats will be controls. All goats will receive four implants epr femur. Each implant will be coated for half of its length with HA, so that each acts as its own comparison control.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Residents have just been assigned as associate investigators Study will begin soon.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-226A

Effects of Coumadin (Warfarin Sodium) on Bone Ingrowth and Attachment Strength in Hydroxapatite-Coated and Uncoated Implants in a Goat Model (Capra hircus).

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Bradley Nelson, CPT, MC, Wayne Johnson, CPT, MC

PERIODIC REVIEW DATE: May 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: To quantify the effects of Coumadin on bone ingrowth and attachment strength using hydroxyapatite coated and uncoated implants.

TECHNICAL APPROACH: Six goats will be assigned to one of two groups, based upon time to euthanasia at 12 or 26 weeks. Four rods will be placed into each femur of each goat. Each rod will be hydroxyapatite coated for half its length. Goats will receive Coumadin for 6 weeks following surgery. After euthanasia, the implants and surrounding tissues will undergo histological and biomechanical analysis.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: Residents have just been assigned to the study. Study will begin soon.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-227

A Double-Blind, Placebo-Controlled Clinical Trial Comparing the Efficacy and Safety of Prolonged Outpatient Enoxaparin and Placebo Therapies in the Prevention of Venous Thromboembolic Disease in Patients Undergoing Elective Primary Hip or Knee Replacement (IND#31,532)

START DATE: Sep 95 EST COMP DATE: Jun 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Mark Clyde, MAJ, MC

PERIODIC REVIEW DATE: 11 Jul 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: IND from sponsor

KEY WORDS: enoxaparin, thromboembolism

OBJECTIVE: The purpose of the study is to evaluate the safety and effectiveness of the outpatient use of enoxaparin vs placebo for the prevention of deep vein thromboses (DVT) following hip or knee replacement surgery.

TECHNICAL APPROACH: Two daily injections post surgery while hospitalized, then two daily injections after discharge for 7 to 10 days. Subjects will be followed with blood tests, blood flow studies (ultrasound), and venogram if necessary. Subjects will be followed for 3 months.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress, recently approved by IRC, pending CIRO approval.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-228A

The Differentiation of Rat Tumors by Placental Lactogen in Rattus norvegicus.

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Harold Vogel, MD

FACILITY/DEPT/SVC: FAMC/Neurosurg

ASSOCIATE INVESTIGATORS: Michael Lieberman, LTC, MS, Ronald Jackson, Ph.D., DAC, Ann Hoyt, M.S., DAC

PERIODIC REVIEW DATE: Jun 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS: rat brain tumor, differentiation

OBJECTIVE: To see if rat placental lactogen can be used to differentiate rat brain tumors (already produced), both in vitro and in subcutaneous transplantation in syngeneic hosts.

TECHNICAL APPROACH: 1) In vitro - attempt at separating out the effects of DMSO and fetal calf serum in bringing about differentiation of rat brain tumors by (a) use of different solvents and/or (b) growing tumor cells in serum-free media; 2) preparation of rat placental lactogen by column chromatography; 3) in vitro and in vivo experiments of see if rat brain tumors will undergo differentiation following exposure to rat placental lactogen

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: ?

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-229A

MRI Evaluation of Denervation and Reinnervation of the Hind Limb
in the Laboratory Rat (Rattus norvegicus)

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael Harnisch, CPT, MC

FACILITY/DEPT/SVC: FAMC/Gen Surg

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Sep 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: See protocol.

TECHNICAL APPROACH: See protocol.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor):

Summary of prior and current progress: None. Recently approved
by IACUC.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-230A

The Fate of Osteochondral Versus Osteoperiosteal Grafts in the Treatment of Surgically Stimulated Osteochondritis Dissecans in a Goat Model

START DATE: EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Jeffrey Hrutkay, LTC, MC

FACILITY/DEPT/SVC: FAMC/Orth Surg

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Sep 95 REVIEW RESULTS: Approved

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: See protocol.

TECHNICAL APPROACH: See protocol.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: None. Recently approved by IACUC.

PUBLICATIONS:

PRESENTATIONS:

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 93/356 (3) Status: Terminated

(4) Title: Correlation Among Parity, Exercise, Age and Urinary Incontinence in the Female Military Member: A Pilot Study

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Gary Davis, LTC, MC (8) Facility: FAMC

(9) Dept of OB/GYN (10) Associate Investigators

(11) Key Words:
urinary incontinence

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 150
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the rate of urinary incontinence in female military members.

(16) Technical Approach: Questionnaires are given to participants after the standard PT test.

(17) Progress: Greater than 150 surveys were returned during the last PT test. We will hand out approximately 200 during the October PT test. FY94: PI wishes to extend this study past the April PT test in order to obtain new subjects and more surveys. FY95: PI failed to provide a final report before PCS from FAMC.

Publications and Presentations: Will be presented at the 1994 Army ACO meeting.

Detail Summary Sheet

(1) Date: 2 May 95 (2) Protocol #: 93/357 (3) Status: Terminated

(4) Title: Quantitation of Urinary Incontinence During Exercise in the Female Military Member

(5) Start Date: 1993

(6) Est Compl Date: 1995

(7) Principal Investigator:
Gary Davis, LTC, MC

(8) Facility: FAMC

(9) Dept of OB/GYN

(10) Associate Investigators

(11) Key Words:
quantitation of incontinence

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Quantify incontinence during simulated PT test in military females complaining of incontinence.

(16) Technical Approach: Pad weighing during exercise.

(17) Progress: 14 subjects have completed the study.
FY94: Only 5 more subjects have completed this study. PI will attempt to isolate more after the next PT test in April.
FY95: Terminated. PI failed to provide final report before PCS from FAMC.

Publications and Presentations: Plan to present results at the 1994 ACO Army meeting.

FY95 DETAIL SUMMARY SHEET FOR GYNECOLOGY ONCOLOGY GROUP PROTOCOLS

Gynecology Oncology Group Protocols. **Terminate.**

80/351 GOG 26A	87/358 GOG 93	89/352 GOG 101
80/352 GOG 26C	87/359 GOG 99	89/356 GOG 102F
80/359 GOG 26S	88/350 GOG 92	90/351 GOG 109
87/353 GOG 90	88/358 GOG 100	91/350 GOG 26II
87/354 GOG 95	88/359 GOG 102A	91/352 GOG 102H

91/353 GOG 109	93/352 GOG 120
91/357 GOG 26LL	93/353 GOG 132
92/351 GOG 119	93/354 GOG 134
93/351 GOG 114	

START DATE: 1980 EST COMP DATE: Indefinite STATUS: Terminated

PRINCIPAL INVESTIGATOR: Francis Major, MD

FACILITY/DEPT/SVC: FAMC/Surg/Gyn

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: May 95 REVIEW RESULTS: Terminated

FUNDING: NA

GIFTS: NA

KEY WORDS: cancer

OBJECTIVE: Cancer treatment.

TECHNICAL APPROACH: Per NCI protocol.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor: NA

Summary of prior and current progress: No new subjects enrolled since the elimination of the position of gynecology oncologist at FAMC several years ago.

PUBLICATIONS: None. PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 11 Jul 95 (2) Protocol #: 82/302 (3) Status: Completed

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84

(6) Est Compl Date: 1995

(7) Principal Investigator:
LTC Richard Harris

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators

(11) Key Words:

microbiology

Donald D. Paine, DAC

microbiological techniques

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: Evaluation of a ELISA kit (Ortho) for the measurement of antibody to hepatitis C (formerly non-A, non-B). This kit appears useful for large scale screening but is not specific enough for confirmation of Hepatitis C. Evaluation of a western blot kit (CHIRON-RIBA) for the measurement of antibody to Hepatitis C in sera. This kit appears to be more specific than the ELISA (ORTHO). We recently evaluated a second generation Western Blot kit (CHIRON-RIBAII) and found it to be more sensitive in detecting antibodies to Hepatitis C in serum than the original RIBA method. Several kits are under consideration including Hepatitis D and a DNA probe for H. influenza.

Progress continued -

Evaluation of an ELISA kit (Whittaker), RheumELISA, for the detection of autoantibodies to Sm, RNP, SS-A/Ro, SS-B/La. Patients with a positive ANA screen were tested using this kit. It was found to be too sensitive for clinical use. Several kits are under consideration for evaluation including an ELISA for Helicobacter pylori.

Evaluation of new Group A streptococcus rapid test procedure is in progress in coordination with the Dept of Pediatrics.

FY94: Completed study of rapid Group A Strep test supporting Department of Pediatrics which was presented at the May 94 meeting of the American Society of Microbiology in Las Vegas. Performing study on new susceptibility test for bacteriology specimens.

FY95: Study completed for DCI purposes.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985; c) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Harris, R: Impact of Rapid Group A Strep Optical Immunoassay Test on Antibiotic Usage in Pediatric Clinics. Am Society of Microbiology, Las Vegas, NV, May 94.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

Detail Summary Sheet

- (1) Date: 7 Feb 95 (2) Protocol #: 89/302 (3) Status: Ongoing
-
- (4) Title: Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus
-
- (5) Start Date: 1989 (6) Est Compl Date: 1996
-
- (7) Principal Investigator: Scott Bennion, COL, MC (8) Facility: FAMC
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- (9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators:
-
- (11) Key Words: Lela Lee, MD, UCHSC
neonatal lupus erythematosus Ann Hoyt
autoantigens Michael Lieberman, LTC, MS
autoantibodies Kathleen David-Bajar, LTC, MC
Ro
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: The major objectives of this project are to characterize the autoantigens and autoantibodies involved in neonatal lupus erythematosus (NLE) and subacute cutaneous lupus erythematosus (SCLE) and to determine if certain characteristics of the autoantigens or autoantibodies can be related to the major clinical findings in these diseases.
-
- (16) Technical Approach: Immunoblotting technique, cloning of Ro, rabbit immunization with Ro to attempt to produce animal model.
-
- (17) Progress: Techniques of Western Blotting are being improved, including comparison of different antigen extracts. Additional patients with subacute cutaneous lupus erythematosus and neonatal lupus erythematosus have been evaluated with Western Blotting. No progress since the FY93 Annual Progress Report.
FY95: There have been no new SCLE or NLE patients seen/enrolled since last progress report. We are currently developing immunoelectron microscopy techniques to visualize the location of the Ro antigen at the ultrastructural level.

Presentation: European Society for Dermatologic Research, Copenhagen, Denmark, June 1991. "Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence".

Abstract: David KM, Bennion SD, DeSpain JD, Golitz LE, Lee LA: Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence.

Publication: David-Bajar KM: Subacute cutaneous lupus erythematosus. J Invest Dermatol 100:2S-8S, 1993.

Detail Summary Sheet

(1) Date: 6 Jun 96	(2) Protocol #: 91/300	(3) Status: Ongoing
(4) Title: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents		
(5) Start Date: 1991	(6) Est Compl Date: 1997	
(7) Principal Investigator: Wheaton Williams, MAJ, MC	(8) Facility: FAMC	
(9) Dept/Svc: DCI	(10) Associate Investigators: David Cohn, MD, DH&H Chip Schooley, MD, UCHSC Douglas Mayers, MD, WRAIR Harris, Richard W., LTC, MS	
(11) Key Words: antiretroviral		
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this Report	(13) Est Accum OMA Cost:*	
(14) a. Date, Latest IRC Review: Jun b. Review Results: c. Number of Subjects Enrolled During Reporting Period: NA d. Total Number of Subjects Enrolled to Date: NA e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"		
(15) Study Objective: To provide a resource collection of lymphocytes and clinical information on HIV infected patients who are taking antiretroviral agents in known amounts and duration on other protocols.		
(16) Technical Approach: Update of history and physical parameters every 12 weeks, collection of 2 x 10 ⁷ lymphocytes after CD4 helper enumeration, beta-2 microglobulin and P24 antigen every 12 weeks, chem 18 every 12 weeks, skin testing every 12 weeks (desirable but not essential).		
(17) Progress: Banking of lymphocytes and collection of clinical data is successfully progressing with a total of 650 patients currently enrolled, 6527 separate data collection times and over 38,000 specimens banked for serum and/or lymphocytes. FAMC Data Base for patient history and plasma/serum/cell collection is being integrated into the central MMCAR data base in coordination with Program area 2. We are initiating a collaboration with Dr. Vahey, Program area 5 in coordination with Wilford Hall (Dr. Melcher). FAMC Data Base files have been sent to the Area 5 Data Manager. We are planning a coordinated evaluation of the FAMC plasma/serum/cell bank for evaluation of surrogate markers in long term HIV patients. No progress during FY95.		
Presentation: The Duration of Clinical Stabilization with AZT Therapy; D.L Mayers et al: International HIV Conference.		

Detail Summary Sheet

- (1) Date: 1 Nov 94 (2) Protocol #: 92/300 (3) Status: Terminated
- (4) Title: Studies on Mycobacterium avium. I. Determination of the Minimum Inhibitory Concentration (MIC) and the Minimum Bactericidal Concentration (MBC) of Various Anti-Mycobacterial Agents and Synergistic Effects with Combinations of Agents
- (5) Start Date: 1992 (6) Est Compl Date: 1994
- (7) Principal Investigator: Michael Lieberman, LTC, MS (8) Facility: FAMC
- (9) Dept of DCI (10) Associate Investigators
LTC Richard Harris, MS
Donald Paine, DAC
- (11) Key Words:
antibiotic synergy
mycobacterium avium
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: (1) Determine values for the MICs and MBCs for each antibiotic with each of the study strains of M. avium; (2) calculate the MIC 90 and MBC 90 values for each antibiotic (the MIC or MBC for at least 90% of the strains, respectively); (3) calculate an index of synergy for various combinations of anti-mycobacterial agents by determining MIC and MBC values for each agent in the presence of fractional MIC or MBC concentrations of the other agents and in the absence of other agents.
- (16) Technical Approach: Laboratory benchwork as described in technical detail in the protocol methodologies.
- (17) Progress: MIC's of 7 antimycobacterial agents have been determined for 3 strains of M. avium and the synergistic potential of various combinations of two of these antibiotics determined. However, further progress is delayed indefinitely due to lack of personnel to support this protocol. FY95: No progress during past year due to lack of personnel and time to support this protocol. This will likely not change in the coming year; therefore, terminate protocol.

Publications and Presentations: None

Detail Summary Sheet

- (1) Date: 1 Nov 94 (2) Protocol #: 92/301 (3) Status: Terminated
- (4) Title: Molecular Epidemiological Studies on Bacterial Isolates from Patients on Intensive Care Units and Other Wards at FAMC
- (5) Start Date: 1992 (6) Est Compl Date: 1993
- (7) Principal Investigator: Richard Harris, LTC, MS (8) Facility: FAMC
- (9) Dept of DCI (10) Associate Investigators Don Paine
- (11) Key Words: bacterial isolates, epidemiology
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: Determine feasibility of epidemiological typing of bacterial isolates by plasmid analysis.
- (16) Technical Approach: A minilysate procedure was used for rapid extraction of several groups of clinical isolates. Whole plasmid extracts and restriction enzyme digests were compared.
- (17) Progress: The technique was found to be useful in strain comparison of several species of clinical isolates. Comparisons of clusters of infections are now being performed. FY94: A comparison was made of several isolates of staphylococcus epidermidis to determine the possibility of pneumoniae and septicemia in a patient and the plasmid analysis proved useful. We should continue these types of studies as need arises for epidemiological investigation. FY95: Due to downsizing this study is no longer necessary.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 8 Sep 95 (2) Protocol #: 92/306A (3) Status: Completed

(4) Title: Evaluation of the Blacktailed Prairie Dog Cynomys ludovicianus as a Model for Hepadnavirus Replication

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Kenneth E. Sherman, MAJ, MC

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators
MAJ Ron Banks

(11) Key Words:

CPT Michael Quintana
Dr. Anthony Gutierrez

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date: 110

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) Test 3 Hepadnavirus for viability in prairie dog model; b) survey wild population for hepadnavirus infection.

(16) Technical Approach: (a) Lab infection with known virus; (b) Field collection and evaluation of serum and tissue for liver damage and infection.

(17) Progress: 110 subjects have been tested to date. FY95: All animal use phases completed. Data analysis pending.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-301

One Time Use of Thymosin Alpha-1 for the Treatment of Hepatitis B
in a Patient with Decompensated Liver Disease

START DATE: Nov 93 EST COMP DATE: Nov 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Dirk Davis, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Clin Invest/Gastro

ASSOCIATE INVESTIGATORS: Robin Creager, RN, Kenneth Sherman, MD

PERIODIC REVIEW DATE: 6 Dec 94 REVIEW RESULTS: Continue

FUNDING: NA GIFTS: NA

KEY WORDS: Hepatitis B, thymosin alpha-1

OBJECTIVE: Treatment of a single subject who has evidence of
decompensated liver disease and who was not able to tolerate the
FDA approved interferon therapy.

TECHNICAL APPROACH: Six-month treatment by injection of thymosin
alpha-1 with 6-month followup.

PROGRESS:

Number of subjects enrolled to date: 1

Number of subjects enrolled for reporting period: 1

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None.

Summary of prior and current progress: No progress to report.
FY95: Final report dated 22 May 95. Therapy with Thymosin Alpha
1 was initiated 3 Jan 94. The patient's baseline ALT level was
159 IU/L. HBV DNA several months earlier was positive by
hybridization assay. The patient was treated on protocol until 20
Apr 94, when a compliance review revealed that the patient had
been taking Interferon alfa 2-b in a random manner on some days
instead of Thymosin alfa-1. Therapy was temporarily halted.
Thymosin alone was restarted 6 May 95. The patient's baseline
ALT was 142, and his viral titer by the Chiron B DNA assay was
 1.064×10^9 HBV DNA equivalents ml. As per protocol, the patient
was treated and followed on a monthly basis for a total of 24
weeks. On 25 Oct 94, Thymosin Alfa-1 therapy was discontinued.
The patient's ALT was 126 and his HBV DNA was quantitated and
found to be 7.87×10^8 . The patient completed the six month
followup phase. The quantitative HBV DNA data from the followup
phase is not available. However, the patient's transaminases
appear to be relatively unchanged, and he clinically continues to
show progressive deterioration associated with his chronic liver
disease.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-302A

Training for Animal Resources Service Personnel in Medical Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species

START DATE: 1 Aug 94 EST COMP DATE:1996 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kevin Corcoran, MAJ, VC

FACILITY/DEPT/SVC: FAMC/Clin Invest/Animal Res

ASSOCIATE INVESTIGATORS: Charmaine Chase, Penelope Giese

PERIODIC REVIEW DATE: 30 Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: training, animals

OBJECTIVE: To provide training in routine and emergency medical, surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation using government-owned animals.

TECHNICAL APPROACH: Proficiency in routine methods and animal emergencies must be developed and maintained by personnel requiring knowledge of the procedures used in working with laboratory animals. This training will enable the individual to perform tasks with expediency and efficiency and with minimal trauma to the animal.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Didactic training only to date. FY95: Eleven persons received training this period using 4 goats, 6 rabbits and 2 opossums.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-303

Laboratory Immunological Studies on Immunodeficiency,
Autoimmunity, Leukemia, Lymphoma, and Breast Cancer

START DATE: Sep 94 EST COMP DATE: Indef STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael Lieberman, LTC, MS

FACILITY/DEPT/SVC: FAMC/Clin Invest/Immun

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Oct 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: immunology tests

OBJECTIVE: To provide clinically relevant diagnostic and
prognostic information with therapeutic implications.

TECHNICAL APPROACH: To perform immunodiagnosis, immunological
classification, and clinical correlation of disorders of
immunodeficiency, autoimmunity, immunoproliferation and
hypersensitivity using specialized tests as requested by
clinicians on a consultative basis.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: This protocol is an
update of a previously approved, long-standing study.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-300

An In Vitro Model for Investigation of Herpes Simplex Virus
Latency in the Skin

START DATE: EST COMP DATE: STATUS: Terminated

PRINCIPAL INVESTIGATOR: Scott Bennion, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Surg

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE:

TECHNICAL APPROACH:

PROGRESS:

 Number of subjects enrolled to date:

 Number of subjects enrolled for reporting period:

 Nature and Extent of Significant Adverse Events (reported to
 the FDA or sponsor):

Summary of prior and current progress: No progress.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-301

Development and Analysis of a Sensitive and Specific Assay to Detect Melanoma Cells in the Peripheral Blood of Patients with Melanoma

START DATE: May 95 EST COMP DATE: May 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scott Bennion, COL, MC

FACILITY/DEPT/SVC: FAMC/Clin Invest

ASSOCIATE INVESTIGATORS: Anthony Gutierrez, PhD, Judith O'Brien, Patrick Walsh, MD

PERIODIC REVIEW DATE: May 95 REVIEW RESULTS: approved

FUNDING: none

GIFTS: none

KEY WORDS: melanoma, metastatic, RT-PCR, peripheral blood

OBJECTIVE: Develop early detection of metastatic melanoma by RT PCR of peripheral blood samples.

TECHNICAL APPROACH: CDNA synthesis from Tyrosine gene message followed by PCR amplification and detection on agarose gels.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): none

Summary of prior and current progress: Have developed procedure and am currently attempting to make it more reproducible.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-302A

Ras Mutations Induce Tumor Progression, Invasion and Metastasis
in Malignant Melanoma

START DATE: Oct 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scott Bennion, COL, MC

FACILITY/DEPT/SVC: FAMC/Clin Invest

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Sep 95 REVIEW RESULTS: Approved.

FUNDING:

GIFTS:

KEY WORDS:

OBJECTIVE: See protocol.

TECHNICAL APPROACH: See protocol.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: No progress. Protocol
recently approved by IACUC.

PUBLICATIONS and PRESENTATIONS: None.

Detail Summary Sheet

- (1) Date: 6 Jun 95 (2) Protocol #: 92/423 (3) Status: Terminated
- (4) Title: Development of a Placental Trophoblast Cell Culture for the in Vitro Study of Placental Metabolism
- (5) Start Date: (6) Est Compl Date: 1997
- (7) Principal Investigator: Beverly Anderson, LTC, MC (8) Facility: FAMC
- (9) Dept of PEDS/Newborn (10) Associate Investigators
Ron Jackson, Ph.D
- (11) Key Words: tissue culture placental trophoblast
Ann Anderson, MD, UCHSC
Fred Battaglia, M.D., UCHSC
Ann Anderson, MD
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
- *Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: To develop an in vitro placental trophoblast culture for human placental trophoblast to study basic normal and abnormal metabolism.
- (16) Technical Approach: In vitro cell culture; tracer studies with stable or radioactive isotope labelled substrates.
- (17) Progress: We have made great progress in use of the choriocarcinoma cells to establish techniques and methods for study, the human placental cells are growing well and ready for study at this time, and work with the sheep placenta will be undertaken this next academic year. FY94: Progress was impeded due to staffing problems. Grant proposals are currently being prepared for continued work. Supplies and resources are currently available to re-initiate studies.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 Jan 95 (2) Protocol #: 93/402 (3) Status: Ongoing

(4) Title: The False Negative Rate of the Denver II in the Fitzsimons Army Medical Center Pediatric Population 7-36 Months of Age

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: David Burgess, MD, DAC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators
J. Householder
C. Spicer
L. Smith

(11) Key Words:
screening
child development
Denver II

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 55
d. Total Number of Subjects Enrolled to Date: 55
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine false negative rate of Denver II; this will allow calculation of sensitivity and specificity of the Denver II as a screening test.

(16) Technical Approach: Will test all children with normal Denver II results over a 24-month period (N=400).

(17) Progress: Study will begin 1/94. Personnel recently completed training with the Revised Bayley Scales of Infant Development which will then be used as the "gold standard". The new test was published Sept 93.
FY95: Study setbacks include training of personnel and contractor problem in providing qualified personnel to do testing in a timely manner. It is hoped that at least 200 children can be tested by the end of 1995 so that there will be enough numbers to validate this research.

Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: 4 Apr 95 (2) Protocol #: 93/417 (3) Status: Completed
-
- (4) Title: Identification of Family Strengths and Needs Using the Q-Sort Process
-
- (5) Start Date: 1993 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Marjorie Feinberg, DAC (8) Facility: FAMC
-
- (9) Dept of PEDS (10) Associate Investigators
-
- (11) Key Words: MAJ Pat Chandler
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: Apr b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 5 _____
d. Total Number of Subjects Enrolled to Date: 28 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To determine what families perceive as important supports during babies' hospitalization.
- (16) Technical Approach: Parent interview and demonstration of Q-Sort Process to prioritize needs of family.
- (17) Progress: 23 families whose babies meet the criteria for part II eligibility have been interviewed. A total of 40 families is our goal. Completion data is dependent on census in NICU which has been low in the past 2 months. We feel it will take another year to complete the interviews depending on census in NICU. Study is still in progress. FY95: The goal of 40 families could not be reached because the NICU closed in Sep 94. Total number of families interviewed was 29 which was an adequate number to analyze. A second stage of this project is being conducted at Brooke Army Medical Center.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-400

Felbamate Monotherapy in Newly Diagnosed Partial Epilepsy

START DATE: Feb 94 EST COMP DATE: Feb 95 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Brian Ryals, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Ped/Ped Neur

ASSOCIATE INVESTIGATORS: Frederic Bruhn, COL, MC, Michael Coats, LTC, MC

PERIODIC REVIEW DATE: Jan 95 REVIEW RESULTS: Terminated

FUNDING: FACT

GIFTS: Wallace Laboratories, prepackaged drug and placebo

KEY WORDS: epilepsy, felbamate, IND

OBJECTIVE: To determine the efficacy and safety of two dosages of felbamate monotherapy in comparison to placebo in preventing recurrent seizures in subjects with newly diagnosed partial-onset epileptic seizures.

TECHNICAL APPROACH: Approximately 15 patients will be enrolled at FAMC. Eligible patients will be between 14 and 65 years of age will be randomized to felbamate 1200 mg/day, felbamate 2400 mg/day or placebo. The 1200 mg group will begin 1200 mg on the first day of the 52-week treatment period. The 2400 mg group will be titrated to 2400 mg over a 2-week period.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: FDA and Wallace Laboratories have suspended use of the drug.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-402

Use of a Degenerate, Nested Primer PCR Technique for Non-Invasive Detection of Anogenital Human Papillomavirus in Males

START DATE: Mar 94 EST COMP DATE: May 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Anthony Gutierrez, PhD, DAC

FACILITY/DEPT/SVC: FAMC/Ped/Clin Invest/Adol Med

ASSOCIATE INVESTIGATORS: Clive Daniels, CAPT, USAF, MC, Judy O'Brien, BS

PERIODIC REVIEW DATE: Apr 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: human papillomavirus, PCR

OBJECTIVE: To determine the sensitivity and reproducibility of the degenerate, nested primer PCR technique for non-invasive detection of anogenital human papillomavirus in males.

TECHNICAL APPROACH: To collect swabbed epithelial specimens from 10 adult male subjects diagnosed with anogenital condylomata and study using PCR.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: PCR primers designed. Primers synthesized. PCR optimized with positive results. Protocol approved at San Diego Naval Medical center 9/15/94.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-400A

Prophylactic Therapy with Interferon-gamma for Group B
Streptococcal Sepsis in the Neonatal Rat

START DATE: 1/18/95 EST COMP DATE: 6/26/95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Robert Wittler, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Peds

ASSOCIATE INVESTIGATORS: Michael Lieberman, LTC, MSD

PERIODIC REVIEW DATE: REVIEW RESULTS:

FUNDING:

GIFTS:

KEY WORDS: Interferon-gamma, neutrophils, newborn

OBJECTIVE: Determine the effects of interferon-gamma on the
neutrophil oxidative burst and expression of CD11b from newborn
rats and their mothers.

TECHNICAL APPROACH: Blood was obtained by IC puncture from the
rat pups and dams, and the neutrophils were separated.
Neutrophils were incubated with varying concentrations of
interferon-gamma and analyzed by chemiluminescence and flow
cytometry.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: Data collection has been
terminated and presently we are analyzing the data. Preliminary
analysis reveals the pups' neutrophil oxidative burst to be
markedly depressed compared to the dams' and no appreciable
influence of interferon-gamma.

PUBLICATIONS and PRESENTATIONS: pending.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-401

Studies of the Neurologic Exam of Young Infants

START DATE: 7 Mar 95 EST COMP DATE: Indef. STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Beverly Anderson, LTC, MC

FACILITY/DEPT/SVC: FAMC/Peds

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: 7 Mar 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: infants

OBJECTIVE: To further refine neurologic exam tools.

TECHNICAL APPROACH: Further examination of the Neoneuro. This is a cooperative effort with Dr. Ellison at UCHSC.

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: No report submitted by investigators.

PUBLICATIONS: ?

PRESENTATIONS: ?

Detail Summary Sheet

(1) Date: 5 Sep 95 (2) Protocol #: 93/475 (3) Status: Terminated

(4) Title: Clinical Comparability of Two Once-Daily Forms of Diltiazem: Effect of Substitution on Blood Pressure Control

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: Lea Conyers, DAC (8) Facility: FAMC

(9) Dept of Pharmacy (10) Associate Investigators
MAJ John Grabenstein

(11) Key Words: LTC Roger Potyk
Diltiazem, hypertension, comparability MAJ Lisa Johnson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___ Sep ___ b. Review Results: ___
c. Number of Subjects Enrolled During Reporting Period: ___
d. Total Number of Subjects Enrolled to Date: ___ 17 ___
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the comparability of clinical effects of Cardizem and Dilacor in the treatment of hypertension.

(16) Technical Approach: Multicenter retrospective analysis of patient records.

(17) Progress: None, recently approved.

FY94: Seventeen patient records reviewed at Ft. Riley this FY. Anticipate completion of study in 1995.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-475

Can Education and Follow-up by a Pharmacist Improve Tolerance and Compliance with Niacin Therapy?

START DATE: 8/21/95 EST COMP DATE: 6/96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Anita Huttenhower, PharmD

FACILITY/DEPT/SVC: FAMC/Pharm/Ambul Care

ASSOCIATE INVESTIGATORS: Marti Anderson, Denise Pitner, Richard Shea

PERIODIC REVIEW DATE: 6 Jun 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: niacin therapy

OBJECTIVE: To evaluate whether follow-up by a pharmacist in patients started on niacin therapy increases compliance and tolerance of therapy.

TECHNICAL APPROACH: All patients receive handout and oral counseling, then 112 patients will be randomized to either a group who are asked to keep a diary or to the group which will receive weekly phone calls from the pharmacist.

PROGRESS:

Number of subjects enrolled to date: 2

Number of subjects enrolled for reporting period: 2

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): none

Summary of prior and current progress: Two patients studied so far.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-500

Relative Efficacy of the Halstead-Reitan Neuropsychological Test Battery as Compared to Tests of Executive Control System function in Determining Extent and Nature of Brain Dysfunction in Active Duty Soldiers Referred for Neuropsychological Assessment

START DATE: Dec 93 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Donald Taylor, Ph.D., DVAMC

FACILITY/DEPT/SVC: FAMC/Psychiatry/Psychology

ASSOCIATE INVESTIGATORS: Charles O'Hara, MAJ, MS, Bryan Smith, Psy.D.

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: neuropsychological assessment

OBJECTIVE: As per title.

TECHNICAL APPROACH: Forty soldiers without psychiatric or neurologic conditions will be administered a multitude of neuropsychological tests. Two experimental groups of 40 soldiers each administered the identical battery of tests will be studied. One of the experimental groups will be referred for testing subsequent to closed head injury. The other 40 will consist of soldiers with miscellaneous other disorders who are suspected of brain impairment and have been referred for neuropsychological assessment.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Medical Hold Company personnel have been approached x3 for volunteering for study. Result=0 volunteers. Attempted grant to pay volunteers. Grant rejected. FY95: No progress. Having difficulty getting Med Hold personnel to volunteer. New AI will try to gain volunteers through various sources, including reservists, and Fort Carson soldiers.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-500

A Study of the Underlying Factors Contributing to Multiple Admissions of CHAMPUS Eligible Psychiatric Patients

START DATE: 1 Mar 95 EST COMP DATE: Sep 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Erin Mullin

FACILITY/DEPT/SVC: FAMC/Psych

ASSOCIATE INVESTIGATORS: Richard Evans

PERIODIC REVIEW DATE: Apr 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: psychiatry, recidivism, multiple admissions

OBJECTIVE: To discover the patient demographic which may be related to patient recidivism on Ward 609.

TECHNICAL APPROACH: Data was gathered using historical data located in patients' files and discharge summaries.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: While none of the five demographics of patients' age gender, ethnicity, diagnosis, or marital status was statistically significant in both this study and the reviewed literature in predicting patients recidivism, there was a prevalent theme which suggested a patient's marital status and the severity of their diagnosis (acuity and relapse rate) were most relevant.

PUBLICATIONS: None.

PRESENTATIONS: Sep 95, MAOM Class, U. of Phoenix

Detail Summary Sheet

(1) Date: 11 Jul 95 (2) Protocol #: 80/602 (3) Status: Terminated

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Mike McBiles, LTC, MC (8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators

(11) Key Words:
adosterone
adrenal glands

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: The total number of patients entered into the study at all sites from its start in 1978 thru 1 May 94 is 81. Two subjects were enrolled this annual report period; 1 at FAMC and 1 at WBAMC. Acceptable images of the adrenal glands were obtained in all patients completing the study. The results of all 81 patients imaged since the onset of this protocol have provided useful clinical information. In our experience, the drug has proved both safe and efficacious. Further patient studies will continue to be performed. The protocol is still under the IND process which requires maintenance of the protocol for use.

FY95: Terminated by the Clinical Investigation Regulatory Office.
Publications and Presentations: None

Detail Summary Sheet

(1) Date: 14 Jun 95 (2) Protocol #: 93/602 (3) Status: Terminated

(4) Title: A Prospective Evaluation of Technetium^{99m} Sestamibi in the Detection of Breast Cancer

(5) Start Date: 1993

(6) Est Compl Date: 1994

(7) Principal Investigator:
Marc Cote, MAJ, MC

(8) Facility: FAMC

(9) Dept of RADIOLOGY/Nuc Med

(10) Associate Investigators

(11) Key Words:
Technetium 99m, sestamibi
breast, cancer

Mike McBiles, LTC, MC
Gloria Komppa, M.D.
Thomas Verdon, COL, MC
Sharon Hammond, MAJ, MC
Phillip Mallory, LTC,
Richard Stotler, LTC, MS
Cathy Parsells, MAJ, MC
Bruce Hamilton, LTC, MS

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Aug b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 2

d. Total Number of Subjects Enrolled to Date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To find an imaging modality that can help differentiate cancer from benign lumps or fibrocystic changes seen on mammography.

(16) Technical Approach: SPECT and planar nuclear imaging of women with breast lumps having biopsies will be imaged.

(17) Progress: FY94: Study was held up pending request for H. Jackson Funding. We will submit a request to the IRB to update the protocol to new findings recently announced at national meeting in May 1994 before we proceed any further. FY95: Terminated due to lack of funding. Now published as a modality that is recognized and routinely used.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-600

Simultaneous Transmission/Emission Protocol (STEP) for Attenuation Correction of Breast and Diaphragmatic Attenuation Artifacts During SPECT 99mTc-Sestamibi Myocardial Perfusion Scans in Women Without Coronary Artery Disease

START DATE: Feb 95 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Albert Lambert, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Rad/Nuc Med

ASSOCIATE INVESTIGATORS: Mike McBiles, LTC, MC, Sun Kim, MAJ, MC, Randal Hall, CPT, MC, Jennifer Calagan, LTC, MC, Royce Solano, LTC, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved.

FUNDING: DWHRP \$123,251

GIFTS:

KEY WORDS: myocardial perfusion imaging, attenuation artifacts

OBJECTIVE: To quantitatively evaluate the distribution, severity, extent and prevalence of breast, diaphragmatic and soft tissue attenuation artifacts during myocardial perfusion imaging using 99mTc-Sestamibi in women without coronary disease.

TECHNICAL APPROACH: This is a pilot study for evaluating the breast and diaphragmatic attenuations in 75 women with 1) bra size of C or greater, 2) 10% over upper limits of lean weight, and 3) less than 5% likelihood of having coronary artery disease. The effect on the variables of breast size and body habitus on apparent perfusion will be analyzed to determine if attenuation correction significantly changes the normal limits in the CEQUAL data base.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The imaging table, and STEP specific hardware/software and treadmill equipment are due for repairs/upgrades in the month of Aug 95. Testing of cardio-fan collimators is complete with good results. The patient recruitment process will begin following testing/training of equipment and personnel.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 1 Aug 95 (2) Protocol #: 92/650 (3) Status: Completed

(4) Title: Patient Education Through Record Sharing

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Stuart Smith, M.D., DAC (8) Facility: FAMC

(9) Dept of PCCM (10) Associate Investigators

(11) Key Words:
patient education
record sharing

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Aug b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 54
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the role of patients in cost/quality.

(16) Technical Approach: Partial record sharing.

(17) Progress: To date 35 patients have participate and 30 have completed the initial steps. Ten have completed all steps and 20 mailings went out in Aug 93. FY94: Preliminary information suggests our patients do not know their problems as well as they could. FY95: Completed.

Publications and Presentations: Three papers are in the process of preparation. A poster presentation was accepted for the 15th Annual Conference on Patient Education sponsored by the American Academy of Family Physicians and the Society for Teachers of Family Medicine, Nov 18-21, 1993, at Scottsdale, AZ, and at the same meeting held in Nov 94.

Detail Summary Sheet

(1) Date: Sep 95 (2) Protocol #: 93/650A (3) Status: Ongoing

(4) Title: Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupials

(5) Start Date: 1993 (6) Est Compl Date: Jun 96

(7) Principal Investigator: N.C. Bethlenfalvay, MD (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators: J.E. Lima, DAC

(11) Key Words:
D. Virginiana/marsupialis
purine (deoxy) nucleotide
metbolism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____4_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare red cell purine (deoxy) nucleotide content, synthesis and catabolism in these cells with those of D. virginiana and of human erythrocytes on record.

(16) Technical Approach: Purine (deoxy) nucleotides and activities of adenosine deaminase, deoxyadenosine kinase, (d) AMP deaminase, S-adenosylhomocysteine hydrolase, S-AMP synthetase, will be studied in intact and lysed red cells and spleen extract, by HPLC/liquid radiochromatography.

(17) Progress: Like red cells of D. virginiana, but unlike human erythrocytes D. marsupialis red cells have a high activity deoxyAMP deaminase. S-adnosylhomocysteine hydrolase activity is low in ADA deficient tissues, but high in ADA sufficient tissues.

Publications: Niedzwicki JG, Liou C, Abernaethy DR, Lima JE, et al: Adenosine Deaminase Enzymes of the opossum D. virginiana: initial chromatographic and kinetic studies. Comp.Biochem. Physiol. 111B, 291-298, 1995. Five papers in preparation.

Presentations: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-650

Impact of Patient Carried Records on the Health Care of Active Duty Service Women

START DATE: Sep 94 EST COMP DATE: Sep 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Stuart Smith, MD, DAC

FACILITY/DEPT/SVC: FAMC/Primary Care/Community Med

ASSOCIATE INVESTIGATORS: Thomas Frederiksen-Cherry, MD, J. Powell Data, MS, C. Hanson, LTC, MS

PERIODIC REVIEW DATE: 2 May 95 REVIEW RESULTS: Copmleted

FUNDING: NA

GIFTS: NA

KEY WORDS: health care delivery, patient records

OBJECTIVE: To determine the effect of patient oriented, abstracted patient records.

TECHNICAL APPROACH: Subjects will be 200 women ages 18 to 62 who are patients at FAMC in both primary care and managed care systems randomly assigned to treatment and control groups.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The focus of this work, impact of patient carried records on the health care of active duty servicewomen, was present to the Defense Women's Health Research Program on June 10, 1994. It was subsequently denied funding. Phase I of this project is ongoing in Sep 94. Phase II is being restructured for action at FAMC. FY95: This phase completed, resulted in publication.

PUBLICATIONS: Letter to the Editor, Military Medicine, Dec 93. Sharing the Tools of Primary Care. Military Medicine, Nov 94.

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-650

Patient Education Research in the Outpatient Clinic

START DATE: Aug 95 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Stuart Smith, MD, DAC

FACILITY/DEPT/SVC: FAMC/Med/Adult Prim Care

ASSOCIATE INVESTIGATORS: Robert M. Hamm, PhD, U of OK HSC

PERIODIC REVIEW DATE: 1 Aug 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: patient education

OBJECTIVE: To develop a Personal Profile to record a mutually acceptable Problem List and Medication List.

TECHNICAL APPROACH: Ten patients will abstract their out patient records with the physician's assistance. A cadre of volunteer non-physician abstractors will derive a Personal Profile from the patient's record. The abstracts will then be compared.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress, recently approved.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 6 June 95 (2) Protocol #: 91/702 (3) Status: Ongoing

(4) Title: Effects of a Policy for Managing Children's Pain

(5) Start Date: 1991 (6) Est Compl Date: 1995

(7) Principal Investigator: Cathy Chess, MAJ, AN (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators: Cathy Chess, MAJ, AN

(11) Key Words: pain assessment Monique Laflamme, LT, AN
Jeff Jones, MAJ, AN
Christine Krimbill, LTC, AN

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: June b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine the effects of implementing a policy for pain assessment and management on pain related outcomes.

(16) Technical Approach: A quasi experimental design guides this study. The experimental group will receive training and material to implement the pain management program. On multiple occasions the following dependent variables will be measured: provider attitudes about pain, provider behaviors related to pain, pain related patient-centered outcomes, and cost factors related to recovery.

(17) Progress: The pilot study has been completed and the preliminary data analyzed. The data indicates that some modification to the Child Pain Scale needs to occur prior to the implementation of the tool in the funded 5 year study. Evaluation of this tool indicated most nurses thought it contained relevant content but it was too lengthy, complex, and cumbersome to use in its current form.

The Pain Experience History forms were felt by the nurses to be excellent but the information obtained may need to be transferred to forms at the bedside.

The Poker Chip Tool was felt to be easy to use and easy to obtain valid information on the child's pain but there was concern about giving the tool to the child at the same time that the parent evaluated the child's pain using the tool. Perhaps the child would feel the nurse did not believe the child's assessment of their own pain. Orientation to the tools and program was felt to be appropriate in

time and content but more support during their study for questions/problems may be needed.

The Pain Flow Sheet was assessed to be positive but may also need some minor changes to make the form easier and faster to use.

Although the collection of data for the pilot study has been completed, the Child Pain Scale is being revised and we request that the study be continued to allow for retesting of this tool here. There is minimal risk associated with this tool as it measures a child's behavioral responses to pain and involves mostly observation.

FY94: Originally entitled "Pilot Study for Psychometric Properties of Selected Tools for Pain Assessment and Management in Children". The full proposal was reviewed and approved by the IRC on 7 Dec 93 with the new title as above.

Baseline data collection was completed at the end of Nov 94, and data analysis for this phase is in progress. Review of the data suggests that the tools for measuring pain are meeting the standards set for reliability. Preliminary findings on child and parent satisfaction with pain management suggests that while in the hospital children and parents are more satisfied with nurse than physician management. Telephone interviews reveal that many parents receive little if any information about addressing pain following hospitalization.

The intervention phase which commenced Dec 93 involved five mandatory 30-min educational sessions: (a) Overview of the Pain Management Protocol. (b) Gate Control Theory and Nonpharmacologic Interventions, (c) Pharmacologic Interventions, (d) Observation Assessment Tool, and (e) Poker Chip Tool and Pain Unit staff could attend a class held on the unit or watch the videotape of that class. Implementation will end 31 May 94, and a 6-mo maintenance phase will begin 1 Jun 94. Interestingly, preliminary results of the implementation phase are in congruence with the theory of diffusion of innovations (Rogers, 1983). Personnel on the pediatric unit have demonstrated activities across the five states of diffusion: Awareness, Persuasion, Decision, Implementation, and Re-invention. Results of the baseline and implementation phase will be available upon completion of data analysis.

FY95: The following are the remaining items of involvement for FAMC from now until Dec 95: finishing medical records review; organization surveys in approximately July and November; attitude surveys in approximately July and November; interviews with individuals and focus groups.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: Jan 95 (2) Protocol #: 93/700 (3) Status: Completed

(4) Title: A Pilot Survey of Timing and Utilization of Preventive Examinations at Fitzsimons Army Medical Center

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: Paula Nelson-Marten, LTC, AN (8) Facility: FAMC

(9) Dept of NURSING (10) Associate Investigators
James Hanley, COL, MC
Janet Wilson, CPT, AN

(11) Key Words: preventive examinations

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1114
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this pilot study is the assessment of current utilization of preventive evaluations by active duty and retired beneficiaries of FAMC and members of the 5502d USAR as recommended by ACT, CTF, USPSTF and ACS guidelines. A secondary purpose is to identify the usefulness of the Health Maintenance Survey in identifying the timing and utilization of preventive evaluations.

(16) Technical Approach: Per protocol.

(17) Progress: Enrollment is complete with 1114 to date. Statistical analysis is underway. Anticipate presentation of data at a meeting in the summer of 1994, and possible submission for publication. No final report submitted.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-700

A Comparison of Initial Success Rates for Student Registered Nurse Anesthetists Performing Oral Endotracheal Intubation with the Miller Blade versus the Macintosh Blade

START DATE: May 94 EST COMP DATE: May 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Michael Fitzgibbons, 1LT, AN

FACILITY/DEPT/SVC: FAMC/Nursing/Anesth

ASSOCIATE INVESTIGATORS: Deborah Selber, CPT, AN, Barry Vance, CPT, AN

PERIODIC REVIEW DATE: 2 May 95 REVIEW RESULTS: Completed

FUNDING: NA

GIFTS: NA

KEY WORDS: intubation training

OBJECTIVE: To determine if there is a difference in success rate for the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Miller blade vs the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Macintosh blade.

TECHNICAL APPROACH: Ten novices will be studied at FAMC. Evans ACH will also be used as an additional study site.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Study ongoing.

FY95: The researchers reduced the number of adult intubations to 25 per novice SRNA. There was not a statistically significant difference between success rates for the first 25 adult intubations when a Miller Blade or a MacIntosh Blade was used. The Mann-Whitney U tested for significance level at .071. However, when success rates were compared for the first 10 adult intubations statistically significant data was obtained. The MacIntosh Blade, used by novice SRNA had a higher success rate when compared to the Miller Blade used by SRNAs. The Mann-Whitney U tested for significance at a .021 level. The researchers are completing their thesis, and have submitted an abstract to the AANA for consideration. The researchers plan to defend their thesis 22 May 95 to meet the requirements for graduation from the US Army/U Texas Houston Health Science Center Program in anesthesia nursing.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-701

Identifying Process Variations Via Risk-Adjusted Outcome

START DATE: Oct 94 EST COMP DATE: Oct 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Kathyrn Dolter, MAJ, AN

FACILITY/DEPT/SVC: FAMC/Nursing/Research

ASSOCIATE INVESTIGATORS: Elizabeth Hill, MAJ, AN

PERIODIC REVIEW DATE: Sep 94 REVIEW RESULTS: Completed

FUNDING: Tri-Service Grant

GIFTS: NA

KEY WORDS: practice impact, quality of care

OBJECTIVE: To assess the validity of using risk-adjusted mortality as a screening mechanism to identify variations in practice impacting on quality of care.

TECHNICAL APPROACH: This multi-center study will utilize a combination case control and exploratory descriptive design to assess input, process, and outcome variables of the coronary artery bypass graft surgery patient care process.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Study recently approved at FAMC. FY95: MAJ Dolter completed the study, but otherwise no information was provided.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-702

Relationship of Posttetanic Count and Train of Four Response
During Deep Neuromuscular Blockade Using Vecuronium Bromide

START DATE: Oct 94 EST COMP DATE: Oct 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Burton Stover, CPT, AN

FACILITY/DEPT/SVC: FAMC/Nursing/Anesth

ASSOCIATE INVESTIGATORS: Therese Conner, MAJ, AN, George
Altmann, CPT, AN

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Completed

FUNDING: NA

GIFTS: NA

KEY WORDS: neuromuscular blockade

OBJECTIVE: To describe the relationship between the posttetanic count and the time to the return of the initial response to TOF stimulation when using tactile evaluation of the surgical patient receiving vecuronium bromide.

TECHNICAL APPROACH: A descriptive study design will be utilized to quantify the relationship between PTC and the time interval to the return of first response to TOF stimulation.

PROGRESS:

Number of subjects enrolled to date: NA

Number of subjects enrolled for reporting period: NA

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Recently approved study. FY95: Data collection has been completed and data analysis is now in progress.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-700

Evaluation of a Structured Physical Fitness Program for Pregnant Soldiers: Effects on Weight Gain, Blood Pressure,, Lost Duty Time, Length of Labor, Infant Birth Weight and Score on the First Army Physical Fitness Test Post Delivery

START DATE: Feb 95 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Elizabeth Wanersdorfer, COL, AN

FACILITY/DEPT/SVC: FAMC/Nursing

ASSOCIATE INVESTIGATORS: Elizabeth Hill, MAJ, MC

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: DWHRP \$103,034

GIFTS:

KEY WORDS: exercise, pregnancy

OBJECTIVE: To evaluate the benefits of a structured exercise program for pregnant soldiers.

TECHNICAL APPROACH: Women will be randomized to either self-regulated exercise or a structured exercise program designed for pregnant women, Motherwell Maternity Health and Fitness Program.

PROGRESS:

Number of subjects enrolled to date: 150

Number of subjects enrolled for reporting period: 150

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: At this point in the study, we have approximately 66 percent of our required participants. Because of the type of study being conducted, the major results will not be available until the end of the study.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 6 Jun 95 (2) Protocol #: 93/750 (3) Status: Completed

(4) Title: Inter-Examiner Reliability of the Trigger Point Examination in Myofascial Pain Syndrome

(5) Start Date: 1993

(6) Est Compl Date: 12/93

(7) Principal Investigator:
Steven Shannon, MAJ, MC

(8) Facility: FAMC

(9) Dept of Physical Medicine

(10) Associate Investigators
Dr. Robert Gerwin, MD
Dr. C.Z. Hong, MD
Dr. David Hubbard, MD

(11) Key Words:
trigger points
myofascial pain
inter-examiner reliability

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if four experienced examiners can obtain similar physical examination data when examining for myofascial trigger point characteristics.

(16) Technical Approach: Four physicians will each sequentially examine a series of subjects, male and female, age 18 years and older in groups of 8-10 at a time randomized by a latin square design.

(17) Progress: Most of statistical analysis completed, but some aspects being looked at more closely. First half of paper is in rough draft form. FY95: Statistical analysis completed.

Publications: None.

Presentations: Poster & Platform presentation, MYOPAIN '95, San Antonio, TX, 31 Jul 95: Identification of Myofascial trigger points: inter-rater agreement and the effect of training. Gerwin RD, Shannon S, Hong Z, Hubbard D, Gevirtz R.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-760

Prospective Evaluation of Health-Care Workers Exposed To the
Blood of Patients Infected with Human Immunodeficiency Virus

START DATE: Mar 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Clement Hanson, LTC, MC

FACILITY/DEPT/SVC: FAMC/Clin Svc/Prev Med

ASSOCIATE INVESTIGATORS: SSGT Danny Bishop

PERIODIC REVIEW DATE: 7 Mar 95 REVIEW RESULTS: Continue

FUNDING: NIH/CDC

GIFTS: NA

KEY WORDS: HIV, natural history, data bank

OBJECTIVE: 1) To estimate the risk of HIV infection in health-care workers (HCWs) exposed via the percutaneous, mucus-membrane, or skin route to HIV infected blood, according to type of exposure.

2) To describe the type of devices and the circumstances of the exposures sustained by HCWs.

3) To describe the clinical natural history and development of laboratory markers of HIV infected HCWs enrolled in this project who seroconvert to HIV.

4) To describe the use of post-exposure chemoprophylaxis by HCWs exposed to HIV infected blood.

TECHNICAL APPROACH: Patients will be tested for HIV within 30 days of exposure and asked to complete a questionnaire regarding the exposure ("needlestick") and also to answer personal sexual questions. The HIV testing and questionnaire will be repeated at intervals during the 12 months of the study.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No patients or FAMC personnel enrolled to date in this study. Although needlesticks occur every month at FAMC, there have been no instances reported to Preventive Medicine of a known occupational (needlestick, sharps stick, mucous membrane exposure) exposure to an HIV-infected patient. FY95: No progress.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-800A

Surveillance of Rodent Populations for Hantavirus

START DATE: Mar 94 EST COMP DATE: Indefinite STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Frederick Harrison, Jr.

FACILITY/DEPT/SVC: FAMC/USAEHA-W/Entomological Sciences

ASSOCIATE INVESTIGATORS: Lester Hale, PhD, William Irwin, Ryan Reichenbacker, 1LT, MS

PERIODIC REVIEW DATE: 15 Sep 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: Hantavirus, surveillance

OBJECTIVE: To assess the health threat to the military communities within the USAAEHA-W support area posed by hantavirus.

TECHNICAL APPROACH: Field study. Approved technologies and techniques will be used to capture rodent species known to be infected with the hantavirus organism. Blood samples will be drawn from the tail while the animal is under anesthesia to determine if the rodent is infected. All animals that are negative for hantavirus will be returned to the area where they were trapped.

PROGRESS:

Number of subjects enrolled to date: 457

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Three surveys completed to date, 3 more survey scheduled for remainder of current year. FY95: Twelve military installations (seven thru report period) have been sampled to establish baselines for Hantavirus. New Hantaviruses are being discovered. Approximately eight new installations will be sampled yearly.

PUBLICATIONS: Technical reports sent to each installation surveyed.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-801A

Survey of Tick Vectors and Wild Rodents for the Presence of Borrelia burgdorferi, in the Black-legged Tick, Ixodes scapularis and in the Western Black-legged Tick, Ixodes pacificus with Special Emphasis on Tick Vectors Attached to Various Species of Peromyscus and Neotoma

START DATE: May 94 EST COMP DATE: Indef. STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Lester Hale, PhD, DAC

FACILITY/DEPT/SVC: FAMC/USAEHA-W/Entomol

ASSOCIATE INVESTIGATORS: Todd Walker, Ryan Reichenbacher, 1LT, MS William Irwin, DAC, Frederick Harrison, Jr., DAC

PERIODIC REVIEW DATE: 28 June 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: tick vectors, wild rodents, Lyme disease

OBJECTIVE: As per title to determined the health threat posed to the military community within the USAEHA-W support area. To make assessments, both known and suspected rodent reservoirs will be surveyed for the Lyme disease.

TECHNICAL APPROACH: Rodents will be trapped for collection of ticks, ear biopsies, and vital statistics and returned to a site near where they were trapped. Tick drags will supplement the animal data.

PROGRESS:

Number of subjects enrolled to date: 1042 rodents

Number of subjects enrolled for reporting period: 471 rodents

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: One Lyme disease risk assessment was conducted at Camp Grafton, North Dakota, 27 June - 1 July 1994. A total of 33 rodents processed.

FY95: Since the last summary report, nine installations were surveyed. Ixodes scapularis were found for the first time at Grand Falls Air Force Base, N.D. Lyme disease was found for the first time at Vandenburg Air Force Base, CA.

PUBLICATIONS: Reports were written documenting results for each installation sampled. Respective reports were sent to installation commanders with recommendations.

PRESENTATIONS: None.

Detail Summary Sheet

-
- (1) Date: Jan 95 (2) Protocol #: 89/900 (3) Status: Ongoing
-
- (4) Title: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610)
for Immunization Against Q Fever
-
- (5) Start Date: Unknown (6) Est Compl Date: Ongoing
-
- (7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC
US Army Health Clinics
Dugway Proving Grounds
Dugway, Utah 84022
-
- (9) Dept/Svc: (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 22 _____
d. Total Number of Subjects Enrolled to Date: 43 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Surveillance program to protect high risk
workers.
- (16) Technical Approach: Administered by U.S. Army Research Institute
for Infectious Disease.
- (17) Progress: Endpoint of this study has not been reached.
- Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: Jan 95 (2) Protocol #: 89/901 (3) Status: Ongoing
-
- (4) Title: Continued Evaluation of the Safety and Effectiveness
of Venezuelan Equine Encephalomyelitis Vaccine, TC-83
Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel
IND 142
-
- (5) Start Date: Unknown (6) Est Compl Date: Ongoing
-
- (7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC
US Army Health Clinic, DPG
-
- (9) Dept/Svc: (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 22
d. Total Number of Subjects Enrolled to Date: 43
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Surveillance program to protect high risk
workers.
- (16) Technical Approach: Administered by U.S. Army Research Institute
for Infectious Disease.
- (17) Progress: Endpoint of this study has not been reached.
- Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: Jan 95 (2) Protocol #: 89/902 (3) Status: Ongoing
-
- (4) Title: Evaluation of New Lots of Tularemia Vaccine, Protocol B:
Comparative Assessment of Francisella tularensis
Vaccine, Live, NDBR 101, IND 157
-
- (5) Start Date: Unknown (6) Est Compl Date: Ongoing
-
- (7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC
Dugway Proving Grounds
US Army Health Clinic
-
- (9) Dept/Svc: (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 43
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Surveillance program to protect high risk
workers.
- (16) Technical Approach: Administered by U.S. Army Reserach Institute
for Infectious Disease.
- (17) Progress: Endpoint of this study has not been reached.
- Publications and Presentations: None

Detail Summary Sheet

(1) Date: Jan 95 (2) Protocol #: 89/903 (3) Status: Ongoing

(4) Title: Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel, IND 914

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC
US Army Health Clinic
DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached. No new enrollments for this reporting period.

Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: Jan 95 (2) Protocol #: 91/902 (3) Status: Ongoing
-
- (4) Title: Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication
-
- (5) Start Date: 1991 (6) Est Compl Date: Indefinite
-
- (7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: USAMRIID
CDC
-
- (9) Dept/Svc: (10) Associate Investigators:
-
- (11) Key Words: antitoxin Shannon Harrison, COL, MC,
botulism Ft. Sam Houston, TX
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: The principle objective is to provide the depreciated botulinum antitoxin to individuals who may be exposed to botulinal toxins by foodborne, parenteral, or aerosol routes. A secondary objective is the collection of information regarding reactogenicity and efficacy of the product in humans.
- (16) Technical Approach: Per Medical Research Institute of Infectious Diseases protocol IND 3703.
- (17) Progress: Protocol recently approved by OTSG. One patient enrolled.
- Publications and Presentations: None.

Detail Summary Sheet

-
- (1) Date: 5 Sep 95 (2) Protocol #: 92/901 (3) Status: Ongoing
-
- (4) Title: Army Pregnancy Study
-
- (5) Start Date: 1992 (6) Est Compl Date: 1995
-
- (7) Principal Investigator: Joseph Creedon, Jr., MAJ, MS (8) Facility: FAMC
Ft. Carson, CO
Evans Army Community Hospital
-
- (9) Dept of Occupational Health (10) Associate Investigators
-
- (11) Key Words:
reproductive outcome
occupational factors
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: The purpose of this current investigation is to attempt to quantify risk to the offspring of female soldiers in the U.S. Army by CMF and MOS for the following outcomes: spontaneous abortions, ectopic pregnancies, intrauterine fetal demise, preterm birth, low birth weight infant, preterm and low birth weight infant, and congenital abnormalities.
- (16) Technical Approach: Initially to be conducted as a pilot study at Evans ACH. Multi-center demographic questionnaire will be performed on study group comprised of female soldiers and the comparison group will consist of wives of soldiers.
- (17) Progress: The pilot phase of this study is complete. Amendments to the protocol, questionnaire and consent form were reviewed and approved by the IRC at the 2 Mar 93 meeting. The protocol will be sent to associate investigators at other sites.
- FY94: As of 3 Mar 94, 1196 subjects have been enrolled which include 371 active duty soldiers, 751 spouses, 66 daughters and 8 women classified as other. This population represents a total of 1179.05

Detail Summary Sheet - continuation FY95 92-901

person years of occupational exposure in the soldier populations and 780.25 person years of occupational exposure in the non soldier population. A total of 503 outcomes have been obtained of which 411 were live births. Currently no statistically significant associations have been noted regarding birth weight and eligibility status ($p=0.373$), soldier vs. spouse vs. daughter vs other. Conversely, black race when compared to the non-black cohort has been associated with 228 gm statistically significant lower mean birth weight (2974 gm vs. 3202 gm, $p=0.003$).

A nested case control study has been performed on some of the soldier data. This study has revealed that the overall unplanned pregnancy rate for the active duty soldiers enrolled was 30.5% (113/371), however, the unplanned pregnancy rate for female soldiers residing in the barracks was 77.9% (88/113). All confidence limits were calculated at 95%. The odds ratio for pregnant female soldiers who live in the barracks for unplanned pregnancy was 3.41 (1.99, 5.89) and the odds ratio for pregnant female soldiers never having taken oral contraceptives was 4.17 (2.27, 4.97). This early data has helped to identify the active duty soldier population as a risk group to target for pregnancy prevention. The unplanned pregnancy rate is felt to substantially impact upon readiness, man-hours lost to the soldier's unit, and the dollar cost for medical care.

FY95: A cross sectional study performed on the pooled soldier data from all of the sites revealed that the overall unplanned pregnancy rate for the active duty soldiers enrolled was 46.5%. The unplanned pregnancy rate for female soldiers residing in the barracks was 76.1%. The odds ratio for pregnant female soldiers who live in the barracks for unplanned pregnancy was 4.10 (2.90, 5.81) and the odds ratio for pregnant soldiers never having taken oral contraceptives was 2.89 (1.97, 4.25). This early data has helped to identify the active duty soldier population as a risk group to target for pregnancy prevention. The unplanned pregnancy rate is felt to substantially impact upon readiness, man-hours lost to the soldiers' unit, and dollar cost for medical care.

Relative Risk Estimates:

	<u>RR</u>	<u>CI 95%</u>
previous LBW vs Current LBW Delivery	3.27	1.54, 6.90
LBW vs Soldier Status	1.32	0.90, 1.94
LBW vs Black Race	2.10	1.45, 3.05
Previous Preterm vs Current Preterm	3.45	1.92, 6.18
Preterm Birth vs Soldier Status	1.21	0.82, 1.79
Preterm Birth vs Black Race	1.71	1.16, 2.52

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 3 Jan 95 (2) Protocol #: 93/900 (3) Status: Completed

(4) Title: Fort Riley Health Promotion Intervention Project

(5) Start Date: 1993

(6) Est Compl Date: 1994

(7) Principal Investigator:
Steven Finder, LTC, MC

(8) Facility:
MEDDAC, Ft. Riley, Ks

(9) FRIP

(10) Associate Investigators
SSG Henry Franco, LPN
Frances A. Bollitto, RN
Karen H. Grimes, RD
Melanie T. Richardson, MS
Lynda S. Colston, LPN
Rosita N. Aguigui

(11) Key Words:
health promotion
hospital costs

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
694 families, 1000+ individuals
d. Total Number of Subjects Enrolled to Date: 563 families
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Can a health prevention and promotion program
reduce short-term direct hospital costs.

(16) Technical Approach: Three-arm multi-year study incorporating two
study groups and a control group.

(17) Progress: Since Jan 93, the study has acquired a building,
developed the intervention and study instruments and begun the
intervention. Currently, the project is developing a hospital wide data
base to track hospital outpatient costs. FY95: Site closed, enrollment
completed, analyzing data.

Publications and Presentations: None

Detail Summary Sheet

-
- (1) Date: 5 Sep 95 (2) Protocol #: 93/902 (3) Status: Ongoing
-
- (4) Title: Epidemiology of Prescribed Medication Use Among Active-duty Troops, Retired Soldiers and Their Families
-
- (5) Start Date: 1993 (6) Est Compl Date: 1994
-
- (7) Principal Investigator: Allan Terry, MAJ, MS (8) Facility: Irwin Army Community Hospital
Ft. Riley, Ks
66442-5037
-
- (9) Pharmacy Service (10) Associate Investigators
MAJ John Grabenstein
LTC Roger Potyk
-
- (11) Key Words:
epidemiology, medication
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To quantify use of prescribed medications among active-duty soldiers, retired soldiers, and their families at representative Army posts.
- (16) Technical Approach: Descriptive report of the incidence and prevalence of use of prescription medications among various groups and subgroups during a 9-month interval.
- (17) Progress: None, recently approved study.
- FY94: To date approximately 200,000 prescriptions have been analyzed. The most frequent generic chemical entites dispensed were ibuprofen (3.9% of prescriptions filled), acetaminophen (3.4%), estrogen-progestoge combinations (3.0%), albuterol (2.2%), nifedipine (2.1%), and clotrimazole (2.0%). The most common therapeutic classes dispensed were oral antibiotics (10.8% of prescriptions), nonsteroidal anti-inflammatory drugs (8.8%), and contraceptive drugs (3.8%). The most common presumptive diagnostic groups were infectious disease (17.0%), respiratory (16.5%), cardiovascular (15.5%), and musculo-skeletal (10.1%).
- Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-900

Assessment of Risk Factors for HIV Infection Among Active Duty
U.S. Military Personnel with Documented Recent HIV-Antibody
Seroconversion - Phase II

START DATE: Jan 94 EST COMP DATE: Jan 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Paula Underwood, MAJ, MC

FACILITY/DEPT/SVC: Fort Carson/Evans ACH/Public Health and
Safety

ASSOCIATE INVESTIGATORS: Annelle Price, RN

PERIODIC REVIEW DATE: 6 Dec 94 REVIEW RESULTS: Continue

FUNDING: MRDC, HMJ

GIFTS: NA

KEY WORDS: HIV

OBJECTIVE: To determine specific factors that are associated
with becoming infected with HIV.

TECHNICAL APPROACH: Computer driven survey using questionnaires,
estimate 3 cases and 6 controls per year, per WRAIR protocol.

PROGRESS:

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None.

Summary of prior and current progress: Minor revisions made to
original protocol by MRDC, HMJ. Revised protocol submitted to
IRC, FAMC, 2 Sep 94. FY95: No progress. Protocol recently
revised by MRDC. WRAIR, Preventive Medicine Service has not
implemented the protocol.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-901

Learning and Attention of 5- to 12-Month-Old Infants Who had Hyperbilirubinemia or Polycythemia in the Newborn Period

START DATE: Feb 94 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Ruth Crutchfield, Nurse Practitioner, DAC

FACILITY/DEPT/SVC: Evans ACH/Ped/Fort Carson

ASSOCIATE INVESTIGATORS: Catherine Weir, PhD, Dept of Psychology, Colorado College, Colo Spg

PERIODIC REVIEW DATE: 7 Feb 95 REVIEW RESULTS: Continue

FUNDING: NA

GIFTS: NA

KEY WORDS: hyperbilirubinemia, polycythemia, newborns

OBJECTIVE: The study aims to examine the cognitive development of babies with different neonatal histories.

TECHNICAL APPROACH: Three groups will be considered with 30 subjects in each group: 1) infants who had neonatal hyperbilirubinemia; 2) infants who had polycythemia; 3) infants who did not have any perinatal complications. Infants will be observed for their reaction to habituation and learning tasks.

PROGRESS:

Number of subjects enrolled to date: 66

Number of subjects enrolled for reporting period: 27

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Between 16 Mar 94 and 20 Jan 95, 90 infants have been tested. Of these 8 failed to complete both tasks, and there were equipment failures for 16 others, and 14 had other neonatal complications (e.g., ventilation). This leaves 52 infants in the sample. Of these 52, 37 were in the control group, 11 in the hyperbilirubinemic group, and 4 in the polycythemic group. Investigators request permission to continue the study until 30 babies in each group are obtained.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-900

Pelvic Floor Exercises and the Management of Impotence

START DATE: Nov 94 EST COMP DATE: Mar 95 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Yvonne Anthony, CPT, AN

FACILITY/DEPT/SVC: GLWACH/Internal Medicine

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: 1 Nov 94 REVIEW RESULTS: Approved

FUNDING: None

GIFTS: None

KEY WORDS: impotence, exercise

OBJECTIVE: As per title.

TECHNICAL APPROACH: Clients will attend an educational program which will include the pelvic floor anatomy, general muscle consciousness training, pelvic floor exercise training to strengthen the ischiocavernosus and bulbocavernosus muscles, self digital examination of pelvic floor contractions and instruction in a home exercise program.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor):

Summary of prior and current progress: PI ETS'd without providing a final report.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-901

Influence of Parenteral Progesterone Administration on the
Prevalence and Severity of Mastodynia in Active Duty
Servicewomen: A Multi-institutional Cross-sectional Study

START DATE: Sep 94 EST COMP DATE: Apr 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Stephen Jones, LTC, MC, and Jim Turek,
MAJ, MC

FACILITY/DEPT/SVC: Evans ACH, Fort Carson, CO, and GLWACH, FLW,
MO

ASSOCIATE INVESTIGATORS: multiple

PERIODIC REVIEW DATE: Mar 95 REVIEW RESULTS: Approved

FUNDING: Defense Women's Health Research Program

GIFTS:

KEY WORDS: mastodynia, progesterone, depo-provera, survey

OBJECTIVE: 1) Assess the efficacy of progestones in the
prevention and treatment of mastodynia. 2) Determine the
prevalence and quantitate the severity of mastodynia among active
duty servicewomen. 3) Quantitate the impact of mastodynia on
productivity and military readiness. 4) Assess whether health
care providers are meeting the expectations of women with
mastodynia.

TECHNICAL APPROACH: A study questionnaire will be distributed to
approximately 6% of active duty servicewomen in the United States
between the ages of 18 and 44 in a multi-institutional cross-
sectional study comparing women receiving parenteral
progestones (medroxyprogesterone acetate or levonorgestrel)
with a control group.

PROGRESS:

Number of subjects enrolled to date: 1,300

Number of subjects enrolled for reporting period: 1,300

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): NA

Summary of prior and current progress: At the time of this
writing, 11 gynecology and family practice clinics have obtained
human use approval and are actively enrolling patients. Thus far
1,300 patients have been enrolled, and 533 have returned
completed questionnaires. Control arm accrual is currently
underway as well, and at the time of this writing, questionnaires
have been mailed to 3,449 randomly selected age-matched controls.

PUBLICATIONS/PRESENTATIONS: None.

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-903

Inoculation with Pentavalent (ABCDE) Botulinum Toxoid.
(CDC IND #161)

START DATE: EST COMP DATE: Indefinite STATUS: Ongoing

PRINCIPAL INVESTIGATOR: J. David Laraway, CPT, MC

FACILITY/DEPT/SVC: Dugway Proving Ground, UT

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Jan 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: immunization

OBJECTIVE: Immunization.

TECHNICAL APPROACH: Immunization.

PROGRESS:

Number of subjects enrolled to date: 22

Number of subjects enrolled for reporting period: 22

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): none

Summary of prior and current progress: Continued protection of
personnel on Immunization Surveillance Program.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-904

Mandibular Condyle Angulation Changes Following Bilateral
Sagittal Split Osteotomy with Rigid Screw Fixation

START DATE: Pending EST COMP DATE: 15 months STATUS:
Terminated

PRINCIPAL INVESTIGATOR: James Berwick, LTC, DC

FACILITY/DEPT/SVC: Evans ACH, Fort Carson, CO 80913

ASSOCIATE INVESTIGATORS: Dennis Adamson, LTC, DC, Harvey Hatch,
LTC, MC

PERIODIC REVIEW DATE: 11 Jul 95 REVIEW RESULTS: Approved
Funding: NA
GIFTS: NA

KEY WORDS: CAT, x-ray, jaw

OBJECTIVE: To measure changes in mandibular condyle inclination
following rigid screw fixation of the mandible following
osteotomies. To correlate changes in condylar angulation with
increased TMJ symptoms following BSSRO with rigid fixation.

TECHNICAL APPROACH: Fifty patients will be evaluated pre-
operatively by CAT and x-ray to measure angulation for the status
TMJ. Patients will be followed monthly for 6 months post-
operatively to determine the status of TMJ.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): 0

Summary of prior and current progress: No progress.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-905

Prenatal Nutrition Class: A Comparison of Two Teaching Methods

START DATE: Oct 95 EST COMP DATE: Jun 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Paula Phurrough, DAC

FACILITY/DEPT/SVC: Evans ACH, Fort Carson, CO 80913

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: 5 Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: teaching methods

OBJECTIVE: As per title and thesis proposal.

TECHNICAL APPROACH: One group uses a noninteractive (videorecorded presentation) and the other is the current interactive lecture with question and answer teaching method. Pre- and post tests will be given and compared.

PROGRESS:

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Newly approved study. No progress.

PUBLICATIONS:

PRESENTATIONS:

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-906

The Effects of a Comprehensive Special Needs Program

START DATE: EST COMP DATE: ? STATUS: Terminated.

PRINCIPAL INVESTIGATOR: Tami Kephart, LTC, AN, Evans ACH, Fort Carson, CO 80913

FACILITY/DEPT/SVC: Evans ACH, Fort Carson, CO 80913

ASSOCIATE INVESTIGATORS:

PERIODIC REVIEW DATE: Sep 95 REVIEW RESULTS: Approved.

FUNDING: ?

GIFTS: ?

KEY WORDS: ?

OBJECTIVE: ?

TECHNICAL APPROACH: ?

PROGRESS:

 Number of subjects enrolled to date: ?

 Number of subjects enrolled for reporting period: ?

 Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: Funding for study was denied.

PUBLICATIONS: ?

PRESENTATIONS: ?

Detail Summary Sheet

-
- (1) Date: 15 Sep 95 (2) Protocol #: 93/950A (3) Status:Ongoing
-
- (4) Title: Study to Determine the Effectiveness of the Permethrin Insecticide, PCC-331, Placed in Bait Stations, to Control Flea Vectors of Plague on Tree Squirrels
-
- (5) Start Date: 1993 (6) Est Compl Date: 31 Dec 95
-
- (7) Principal Investigator: Frederick Harrison, Jr., MAJ, MS (8) Facility: FAMC Colorado Dept of Health
-
- (9) Dept of USAEHA-W (10) Associate Investigators Frederick J. Harrison, Jr.
-
- (11) Key Words: plague, fox squirrel
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To determine if a selected insecticide, placed into bait stations, will kill fleas on squirrels thereby reducing the threat of plague in the community. This study is in response to the current plague epizootics among squirrels along the front range of Colorado, in particular Boulder, Colorado Springs, and Pueblo.
- (16) Technical Approach: Squirrels will be live trapped, anesthetized, combed for fleas, ear tagged for identification, and released at the capture site. Bait stations equipped with insecticide impregnated rings at each end will be used to passively apply a small amount of material to the squirrel as it passes into the tube. Thirty days following the baiting, squirrels will again be captured and combed for fleas to determine the effectiveness of the insecticide.
- (17) Progress: Low flea counts in summer 1993 resulted in insufficient data to evaluate the insecticide. Repeat field trials in fall 1994. FY95: Inclement weather prevented Spring 1995 survey of squirrels; will resume trapping and flea sampling in Fall 1995.46 S.niger surveyed to date; 4 S.niger this report period.

Publications and Presentations: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 94-950A

Postgraduate Course on Obstetric, Neonatal and Gynecologic Care:
Resuscitation of the Newborn Utilizing the Ferret Model (Mustela
putorius furo)

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Thomas Harris, MD, NA

FACILITY/DEPT/SVC: FAMC/Neonatology Assoc. Ltd., 300 W.
Claredon, Suite 375, Phoenix, AZ 85013

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 29 Sep 95 REVIEW RESULTS: Approved

FUNDING: NA

GIFTS: NA

KEY WORDS: training

OBJECTIVE: To enable new officers of the Indian Health Service
to become proficient in the life-saving technique of endotracheal
intubation used in neonatal resuscitation.

TECHNICAL APPROACH: Endotracheal intubation of anesthetized
ferrets under supervision of certified animal technicians.

PROGRESS:

Number of subjects enrolled to date: 13

Number of subjects enrolled for reporting period: 13

Nature and Extent of Significant Adverse Events (reported to
the FDA or sponsor): None.

Summary of prior and current progress: All trainees were
proficient in the procedure by the end of the one-hour workshop.
FY95: These sessions consistently receive the highest
evaluations from the students of any of the Workshops offered at
the ACOG/IHS Postgraduate Course on Obstetric, Neonatal and
Gynecologic Care presented annually in Aurora, CO. The
Intubation and Resuscitation of the Newborn Workshop receives
extensive mention and evaluation in the Final Report by ACOG of
its annual Postgraduate Course supported under Contract #282-94-
017 with the Indian Health Service.

PUBLICATIONS: None

PRESENTATIONS: None

FY95 DETAIL SUMMARY SHEET FOR PROTOCOL 95-950

Randomized, Multicenter Evaluation of the Safety and Effectiveness of the Sacral Nerve Stimulation System for the Treatment of Urinary Dysfunctional Voiding Patterns (IDE G850193)

START DATE: ? EST COMP DATE: ? STATUS: ?

PRINCIPAL INVESTIGATOR:

FACILITY/DEPT/SVC: FAMC/?

ASSOCIATE INVESTIGATORS: ?

PERIODIC REVIEW DATE: ? REVIEW RESULTS: ?

FUNDING: ?

GIFTS: ?

KEY WORDS: ?

OBJECTIVE: ?

TECHNICAL APPROACH: ?

PROGRESS:

Number of subjects enrolled to date: ?

Number of subjects enrolled for reporting period: ?

Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): ?

Summary of prior and current progress: ?

PUBLICATIONS: ?

PRESENTATIONS: ?

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